“STUDY OF CLINICAL OUTCOMES OF SUBFASCIAL ENDOSCOPIC PERFORATOR LIGATION SURGERY IN PERFORATOR INCOMPETENCE’’

Dissertation submitted

To

THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY, CHENNAI

With partial fulfillment of the regulations for the award of the degree of

M.S (General Surgery)

Branch-I

Government Kilpauk Medical College

Chennai- April -2016

DECLARATION BY THECANDIDATE

I hereby declare that this dissertation titled "**STUDY OF CLINICAL OUTCOMES OF SUBFASCIAL PERFORATOR LIGATION SURGERY IN PERFORATOR INCOMPETENCE''** is a bonafide and genuine research work carried out by me under the guidance of Prof. USHA DORAIRAJAN MS, FRCS, department of General Surgery, Kilpauk Medical College, Chennai-10.

This dissertation is submitted to **THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY CHENNAI** in partial fulfillment of the degree of M.S. General Surgery examination to be held in **April 2016**.

Date:

Place: **DR. USHA. H**

CERTIFICATE

This is to certify that this dissertation is the bonafide work of

DR. USHA. H

On

"STUDY OF CLINICAL OUTCOMES OF SUBFASCIAL PERFORATOR LIGATION SURGERY IN PERFORATOR INCOMPETENCE''

During her course in M.S. General Surgery from November 2014 to September 2015 at Government Kilpauk Medical College, Chennai-10.

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The Proposal is APPROVED.

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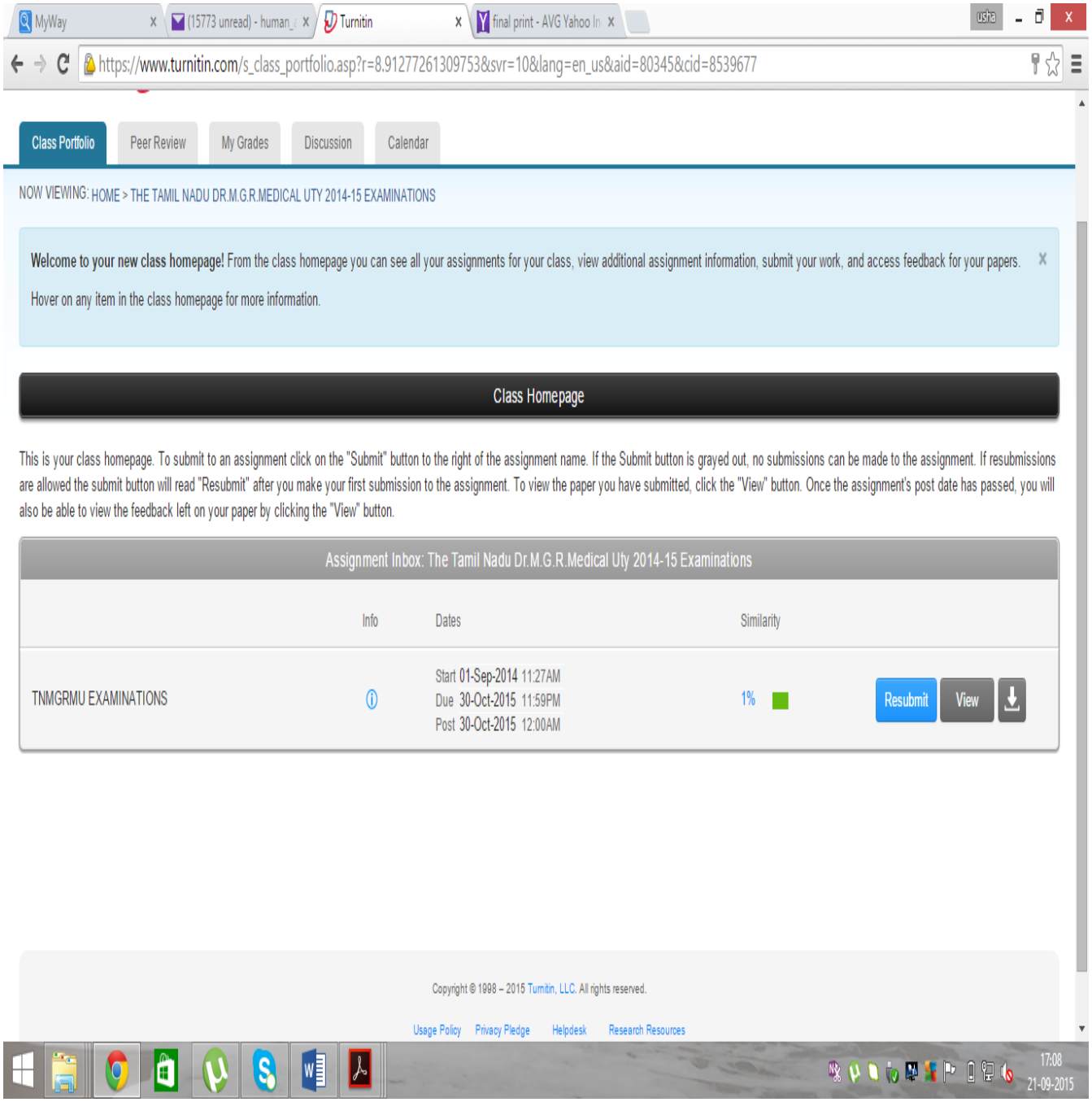
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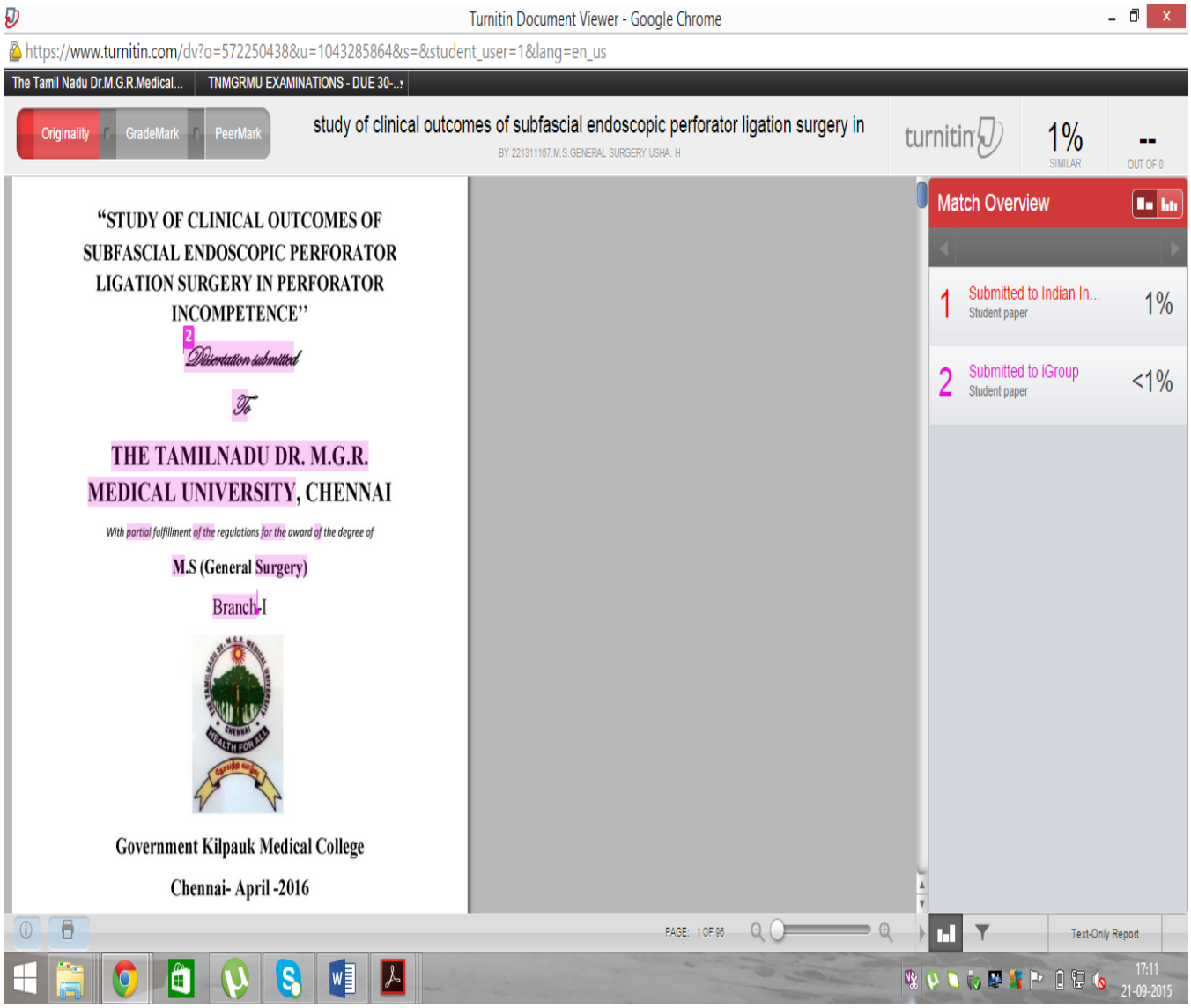
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I would like to thank God for the things he has bestowed upon me .

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ABSTRACT

TOPIC: Study of clinical outcomes of subfascial endoscopic perforator ligation surgery in perforator incompetence

Background: Chronic venous insufficiency of lower limbs leads to major non-fatal disability which are usually managed by non-surgical means. But in advanced cases with active or healed ulceration or with skin changes, the surgical procedure play an important role in reducing the clinical severity of the disease

Methods: A prospective longitudinal study of 30 patients who underwent subfascial endoscopic perforator ligation surgery for incompetent perforator veins of lower limbs in patients with CEAP class 4, 5, and 6 between November 2014 to September 2015. Data was collected from the patients and assessed for Venous clinical severity score and size of ulcer prior to surgery and post SEPS at 1st week, 2nd week and 3rd week

Results: The percentage reduction in clinical symptoms when assessed using VCSS after 3 weeks post SEPS was 36.36% and percentage reduction in size of ulcer was found to be 53.33% after 3 weeks post SEPS

Conclusion: SEPS is a minimally accessible surgery with a feasibility to tackle the incompetent perforators of lower limbs which play an important role advanced chronic venous insufficiency with lower rates of complication, faster recovery and decrease in clinical severity of disease

Keywords: Subfascial endoscopic perforator ligation surgery, Venous clinical severity score, perforator incompetence, varicose veins,chronic venous insufficiency.

TABLE OF CONTENTS

INTRODUCTION

Chronic venous insufficiency presents with a spectrum of clinical features ranging from pain or heaviness of affected limbs to non-healing ulcers over the lower limbs. The development of this chronic venous insufficiency pathology is well attributed to venous hypertension either caused by obstruction, valvular reflux or both involving superficial, deep or perforator veins

The patients with chronic venous insufficiency usually require some form of surgical intervention as aggressive conservative therapy including compression, lifestyle modification and venotonic medications are of high cost treatment with increased risk of increasing symptoms

Primary valvular incompetence leading to cutaneous venous hypertension in 60% of the patients results in a series of cutaneous manifestation which in its severe form presents as ulcers over the medial malleolus. The deep venous system communicates with the superficial system by the perforators with inward flow. Perforator

incompetence is one of the leading cause for chronic venous insufficiency in lower limbs

Many studies have demonstrated that most patients with venous or varicose ulcers or long standing venous insufficiency have a large number of incompetent perforators compared to patients with uncomplicated varicose veins

The surgery for perforators like the stab avulsions or multiple phlebectomies, fails to correct the outward flow in perforators in most cases. This is because, the removal of superficial varicosities do not affect the transmission of high venous pressure from the calf pump to the microcirculation of the skin of the "gaiter area" called as the "blow out syndrome"

The only way to tackle this pathway is by performing direct perforator vein division preferably by subfascial endoscopic perforator ligation surgery for perforator incompetence

This above theory has led the Edinburgh group to have formulated a classification for the incompetent perforator veins and the type of venous surgery suggested in order to correct the outward flow in the perforating veins

EDINBURGH CLASSIFICATION:

TYPE I: Long or short saphenous vein reflux with normal deep venous system. 80% require standard saphenous surgery alone to correct outward flow

TYPE II:

Isolated deep venous reflux without significant saphenous reflux. Subfascial endoscopic perforator ligation surgery is appropriate option as a surgical modality

TYPE III:

Both superficial and deep venous reflux

Standard saphenous surgery combined with subfascial endoscopic perforator ligation is the best option

TYPE IV:

Incompetent perforating vein acts as a collateral bypassing the occluded deep venous system. Perforator interruption is detrimental

TYPE V:

Incompetent perforating veins in the absence of deep and superficial reflux or obstruction. This variety is very rare.

Hence subfascial endoscopic perforator ligation surgery is an appropriate option for all type II and type III incompetent perforating veins reducing the burden of treating the advanced chronic venous insufficiency and in patients with active ulcer falling in the category CEAP 4,5 and 6 with better outcome, efficacy and morbidity.

AIM OF THE STUDY

To determine the results of Subfascial endoscopic perforator vein surgery (SEPS) in perforator incompetence

PARAMETERS TO BE EVALUATED:

1 .Symptom reduction assessed by Venous clinical severity scoring (VCSS) pre-operatively and post-operatively at 1st , 2nd and 3rd week

2 .Rate of ulcer size healing-venous ulcer size assessment pre-operatively and post-operatively at 1,2 and 3 weeks

REVIEW OF LITERATURE

Chronic venous insufficiency is one of the major health and socioeconomic issue throughout the world leading to long term morbidity and high cost of treatment

Varicose veins affects 10-20% men and 25-33% women. For each patient with venous ulcer there are about a 30 patients with lipodermatosclerosis. The prevalence of venous ulceration is approximately about 0.1-0.3% [1] due to chronic venous insufficiency. In USA the prevalence is approximately 1 in 22 or 4.5% or 12.2 million are affected with varicose veins. The prevalence is higher in women approximating their 50's and is estimated to be 41%. Amongst the people affected about 89.5% have a history of long standing hours at work

A chronic venous leg ulcer is defined as an area of discontinuity/disruption of the epidermis of the skin over the lower leg, persisting for more than4 weeks occurring as a result of chronic venous hypertension and calf muscle pump insufficiency [1.] It is a very common problem in clinical practice in Western world. The scarcity of epidemiological studies done on the incidence of this disease reflects a lack of interest

It is a chronic, non- fatal condition that mainly affects the elderly. The reports that are confined to active venous leg ulcers, the point prevalence are reported as between 0.06% and 1 %"[2,3] Because of the recurring cycle of ulcer healing and recurrences the prevalence studies of active ulcers are certainly underestimated the true number of patients. In studies done where patients had a history of ulcer disease (active or currently inactive ulceration) were also included, the overall prevalence is between 1 % and 1.3% of the total population.[4,5] At any time, approximately one-fifth of patients were affected with venous ulcer disease had an active ulcer".

Nelzen and colleagues estimated in a published study in the British Journal of Surgery, [6] "the overall prevalence of lower limb ulceration (open and healed) to be 2.1 %, with a ratio of active: healed ulcers to be 1: 2". They have also found an increased rate of "self- treatment" in the study population, especially in patients who were in their below retirement age which explains the underestimation of prevalence of previous epidemiological studies (which were mainly obtained on postal surveys of general practitioners and the district nurses of the nearby hospitals).

The large Lothian and Forth Valley Leg Ulcer Study, [7] was also based on a postal survey in two health board areas of Scotland (a population of about one million people) reported that "majority of patients suffering from leg ulcers were women and that the condition was more prevalent in the elderly, the median age for men being 67 years (range 22-96) and for women 74 years (range 21-100)"

This is in concordance with Baker et al [8] study who observed that "90% of their Australian patients with venous ulcers were over 60 years (median 75; range 20-99 years) with a distinct female predominance18". The prevalence figures of the Dutch population (1.6% of 15.400.000 inhabitants) was more than 245.000 patients with

12 venous ulcers of the lower leg in the Netherlands. A number that will only grow in future due to aging of the population.

FUNCTIONAL ANATOMY OF LOWER LIMB VENOUS SYSTEM:

The lower limb venous system consists of

1. Superficial venous system
2. Deep venous system
3. Perforating veins

THE SUPERFICIAL VENOUS SYSTEM:

It includes the great saphenous vein or long saphenous vein, small saphenous veins and also the reticular veins

THE GREAT/LONG SAPHENOUS VEIN:

It arises from the medial aspect of dorsal venous arch and ascends anterior to medial malleolus and at the junction of distal and middle third of the calf crosses the tibia to pass posteromedial to the knee. It then ascends medially in the thigh to perforate the

deep fascia and joins the common femoral vein 4 cm below and lateral to pubic tubercle.

In the saphenous compartment ,that is the sub compartment of superficial compartment bordered superficially by saphenous fascia and deeply by muscular fascia, the great saphenous vein lies directly on the muscular fascia and is been described as an “Egyptian eye”.

Lack of this fascia support in this areas have been identified as cause of varicose veins.

True duplication of great saphenous vein is been identified by the splitting of vein into two channels and which later re-join both lying on the muscular fascia of thigh, the incidence of which is 8%in the thigh and 25% in calf

In the calf the great saphenous vein has two main tributaries

1. The anterior branch
2. Posterior arch vein (Leonardo’s vein)

The posterior arch vein begins behind the medial malleolus and joins the great saphenous vein just distal to the knee and drains a network of medial ankle veins. It is important to note that the posterior tibial perforators drain into the posterior arch vein rather than the main trunk of great saphenous vein. Hence procedures that direct towards the great saphenous vein in calf will not take care of incompetent perforators

One or more inter-saphenous veins between the small and great saphenous veins may also have been seen crossing the calf obliquely. In the thigh the anterior and the

posterior accessory saphenous veins, ascends parallel to great saphenous vein external to saphenous fascia.

The venous drainage from the lower abdomen and the perineum namely superficial circumflex iliac, superficial epigastric and superficial external pudendal vein joins the

great saphenous vein near the saphenofemoral junction. A valve is present at this junction .The main trunk of great saphenous vein has at least six valves.

TRIBUTARIES OF LONG SAPHENOUS VEIN

Grouped into 4 groups

1. Posterior arch complex

2. Anterior crural vein- veins ascends directly diagonally across shin of tibia towards long saphenous vein or posterior arch vein

3. Infragenicular vein-drains the skin around the knee and circling below it to join the long saphenous vein

4. Inter-saphenous vein

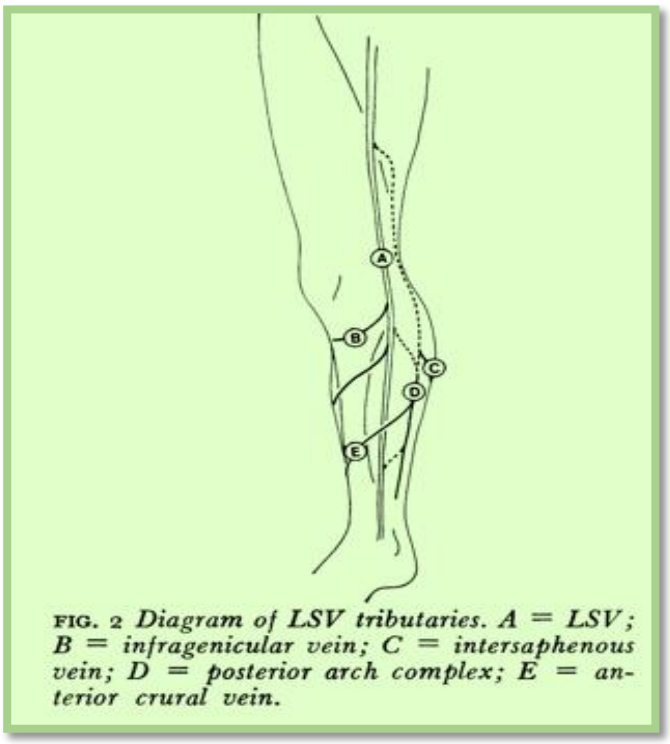


FIG. 2 *Diagram of LSV tributaries. A = LSV; B = infragenicular vein; C = intersaphenous vein; D = posterior arch complex; E = anterior crural vein.*

SMALL SAPHENOUS VEIN:

It is also known as short or lesser saphenous vein. It arises from the dorsal pedal arch and ascends behind the lateral malleolus posterolaterally, penetrates superficial fascia of calf and terminates in popliteal veins at variable distances. Sural nerve lies lateral to short saphenous vein beneath the muscular fascia prior to its termination. Short saphenous vein has closely spared valves approximately 7-10 in number

Vein of Giacomini is the cranial extension of short saphenous vein which may ascend posteriorly in thigh to communicate with great saphenous vein through posterior circumflex vein. The lateral arch vein is its major tributary and it communicates with the peroneal veins through the calf perforators

DEEP VENOUS SYSTEM:

The lower limb major deep veins follows the major arteries. The deep venous system consists of the tibial veins, peroneal veins, soleal veins and the gastrocnemial vein. The venae commitantes of the corresponding arteries namely anterior tibial, posterior tibial and peroneal veins form a plexiform arrangement around the arteries

The soleal sinuses are approximately 1-18 in number communicate with the posterior tibial veins in proximal calf whereas the gastrocnemial network coalesces forming paired gatrocnemial veins draining the popliteal veins which is directly connected to deep femoral vein

There are about 5 deep venous valves from the inguinal ligament and popliteal fossa, the arrangement of which is variable. The peroneal and the tibial veins have a numerous valves which are spared at an interval of approximately 2cm. Popliteal veins have 1-2 valves

PERFORATING VEINS:

Perforating veins are of importance in connection with the problem of varicose veins. These perforator veins perforate the deep fascia are predominantly found below the knee, and vary in number from 90 to 200. They are of varying diameter from less than 1 mm to 2 mm. Van Limborgh [9] using a microinjection technique found about 60 perforators in the thigh, 8 in the popliteal fossa, 28 in the foot and 5 in the leg. Sometimes small arteries, lymphatic vessels cutaneous nerves may accompany the perforators through the same fascial opening".

Most of these perforators are seen to occurs along a 3cm wide lane on the medial calf surrounding what is been called the “LINTON’S LINE”

Le Dentu [10] originally described the perforating veins as

1. Direct perforators[11] which pass directly from the superficial veins into the deep veins. The direct perforating veins are more constant in position, larger and hemodynamically are more important than the indirect perforating veins

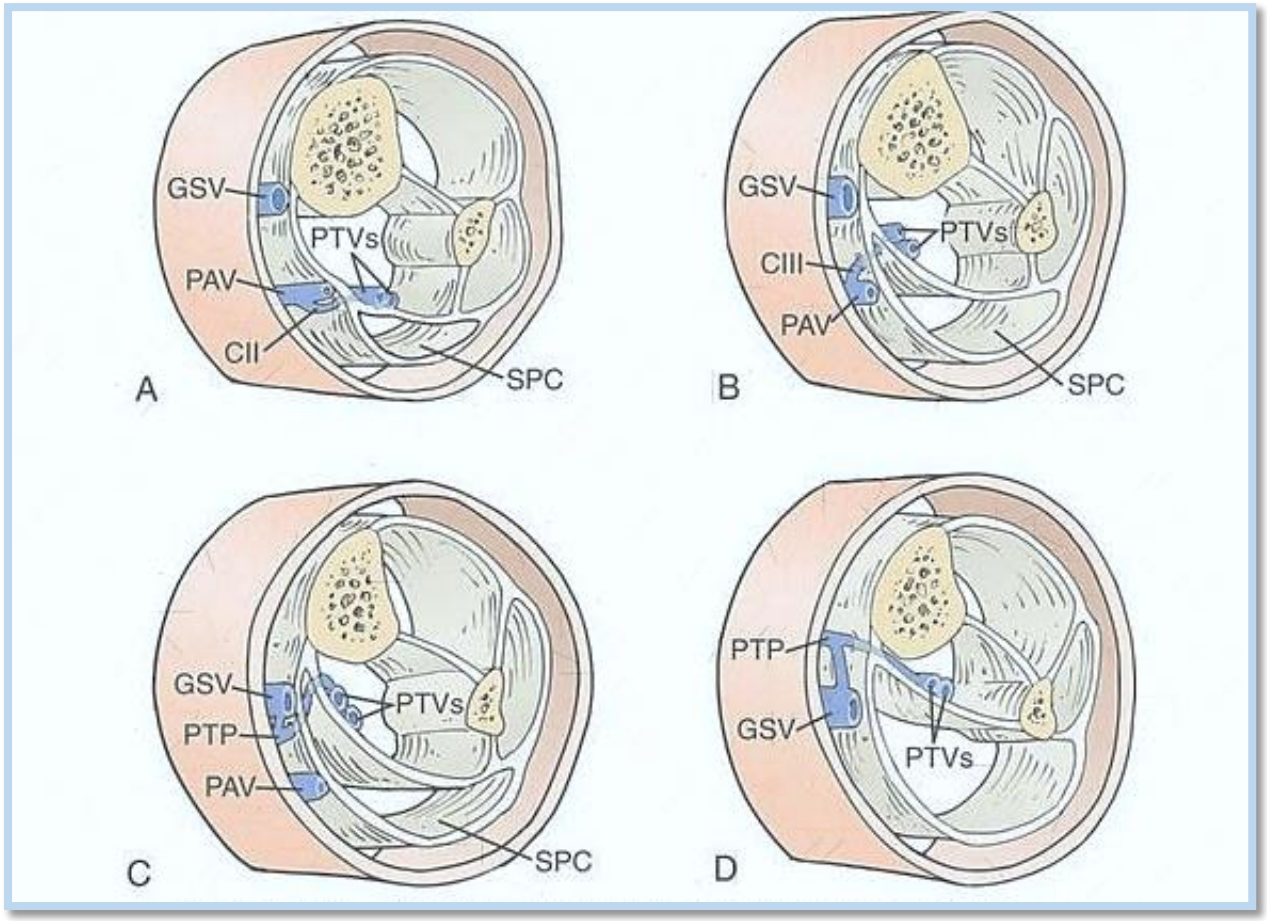
The direct perforators are localized in 5 groups depending upon the distance from medial malleolus which is as follows: (i) 7-9 cm (ii)10-12 cm (iii)18-22cm (iv)23-27 cm (v) 28-32cms

2. Indirect perforators interrupt their course into muscular venous channels i.e., the venous sinuses before terminating in the deep system.

According to Gay[12], “the perforating veins usually start from subcutaneous veins of secondary size i.e, tributaries of the saphenous trunks, and not from the main vessels". There are about 50 and 100 unnamed indirect perforators that enter the muscles before they join the deep veins. They may be accompanied by a small artery and are primarily the accompanying veins of small cutaneous arteries. They are not very important but may dilate and become hemodynamically significant following events like deep vein thrombosis and post thrombotic event like recanalization and reflux. Clinically the direct perforating veins are more important. The great saphenous vein have two direct communications with the deep venous system of the thigh. One is the

entrance in the common femoral vein and another is the constant perforating vein approximately 15 cm proximal to the level of the knee named as Hunterian perforator

The remaining direct perforating veins of the leg may not communicate directly with the long saphenous vein but may communicate with its tributaries.



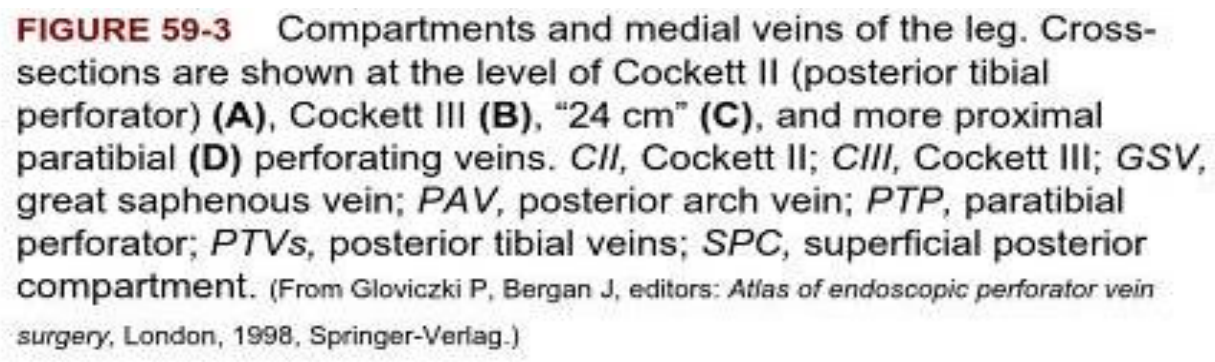


FIGURE 59-3 Compartments and medial veins of the leg. Cross-sections are shown at the level of Cockett II (posterior tibial perforator) **(A)**, Cockett III **(B)**, "24 cm" **(C)**, and more proximal paratibial **(D)** perforating veins. *CII*, Cockett II; *CIII*, Cockett III; *GSV*, great saphenous vein; *PAV*, posterior arch vein; *PTP*, paratibial perforator; *PTVs*, posterior tibial veins; *SPC*, superficial posterior compartment. (From Gloviczki P, Bergan J, editors: *Atlas of endoscopic perforator vein surgery*, London, 1998, Springer-Verlag.)

Perforating veins of lower limbs are grouped into 4 groups of clinical significance:

1. **Foot perforators**:

   They normally direct flow towards superficial veins unlike others which normally direct flow from superficial to deep system

2. **Medial calf perforators:**

   Of particular interest amongst the perforators are a series of about six medial calf perforators (often called Cockett's veins) that joins the posterior tibial vein through superficial veins known as the posterior arch vein. It is the main tributary of the Long saphenous vein in the lower leg. This vein arises as a result of the confluence of a number of calcaneal branches posterior to the medial malleolus. This vein ascends on the posteromedial aspect of the leg and terminates at a variable distance below the knee by entering the Long

saphenous vein. This vein communicates directly with the deep venous channels via the medial leg perforators. Thus in the erect position the essential venous drainage of the ulcer bearing area is taken directly into the deep veins, not into the saphenous system. Hence the effects of venous incompetence in the long and short saphenous systems can reach this area via the connections with the venous arches which link these perforating veins.so stripping of the Long saphenous vein from groin to ankle do not interrupt these calf perforating veins.

3. **Lateral calf perforators:**

   Substantial perforators stemmed from the SSV or the inter-saphenous vein to sink into the gastrocnemius in most individuals

4. **Thigh perforators**

   The 'Hunterian' perforator leaves the LSV in the thigh and passed deep and behind the posterior border of the sartorius and joins the femoral veins or their muscular tributaries

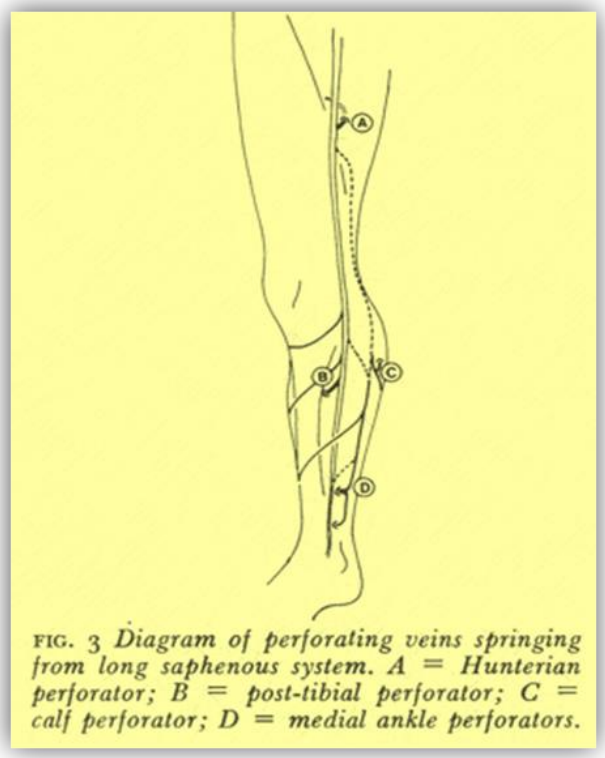


FIG. 3 *Diagram of perforating veins springing from long saphenous system. A = Hunterian perforator; B = post-tibial perforator; C = calf perforator; D = medial ankle perforators.*

Medial ankle perforators:

An elongated triangle on the medial aspect of the lower half of the leg is present which is bounded by the subcutaneous border of the tibia, below by the flexor retinaculum and anteriorly by the anterior border of the soleus. It pierces the fascial roof and communicates directly with the posterior tibial venae comitantes. The size, number, and origin of these perforators vary. The length of these perforators depends on their position in the triangle. Inferiorly they are shortest about 1 cm long, the posterior tibial vessels lie immediately beneath the fascial roof. Towards the apex they are 3-4 cm inwards between the soleus and flexor digitorum longus to reach their destination. Competent valves are seen in each of the normal-looking perforators

FIG. 5 *Diagram of the 'venous triangle', the elongated space between the subcutaneous tibial border and soleus, showing the medial ankle perforators in their short and unsupported course from the posterior arch complex to the posterior tibial venae comitantes.*

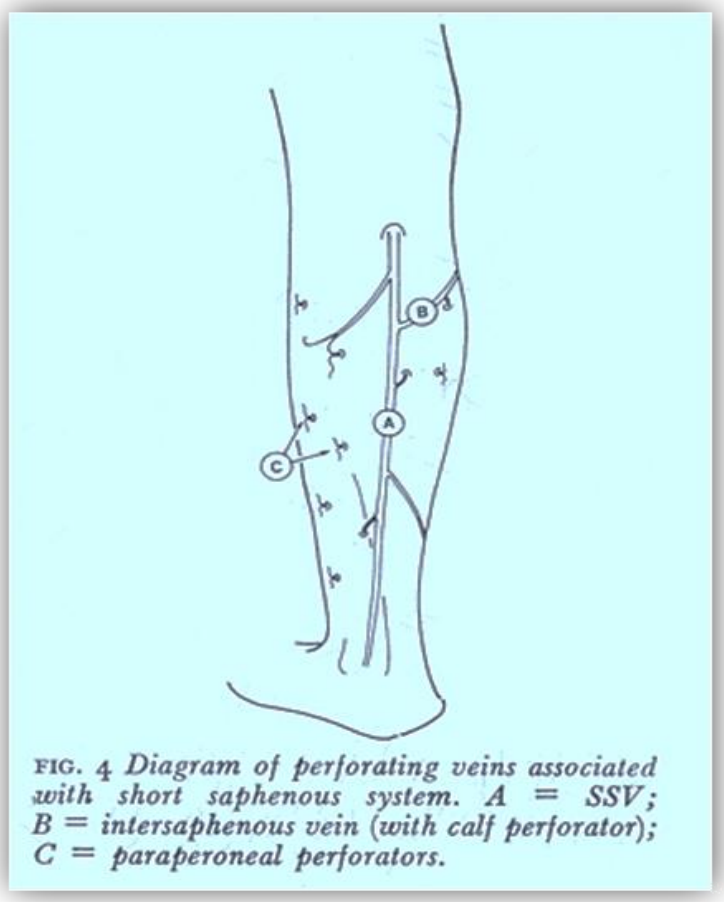


FIG. 4 *Diagram of perforating veins associated with short saphenous system. A = SSV; B = intersaphenous vein (with calf perforator); C = paraperoneal perforators.*

The medial ankle perforators differ from the rest of the perforators for the fact that they have a relatively long course and are firmly buttressed by surrounding tissues. In the 'venous triangle' they are short and unsupported in the wide interval that lies in between soleus and flexor digitorum longus. In addition to this they open directly into the posterior tibial venae comitantes and positioned in an area singularly exposed to trauma. They are thus uniquely endowed with the potential for valvular damage that may occur from either direct injury or from extension of deep vein thrombosis. In either case, the entire length of these perforators is likely to be involved and ill-effects of venous hypertension can be transmitted directly to the subcutaneous tissue and skin

The perforator veins should not be confused with the communicating veins. Each perforator at least has one bicuspid valve subfascial unidirectional valve that allows blood to flow from the superficial veins to deep veins (inward flow) Normal outward flow (flow direction from perforating vein to superficial vein) is 350ms. Anything more than 350ms is defined as reflux
Normal perforators have a subfascial diameter of less than 3 mm. Any thing more than 3.9mm is considered as cut off valve for reflux. Labropoulos et al [13] indicated that the diameters of perforators larger than 3.9mm was predictive of reflux.

The calf perforating veins are normal, abnormal but competent, incompetent or severely incompetent with diameter as follows- 1.5mm,

2.5 mm,3.5mm and 4.5mm respectively

Any perforator lying beneath an active or a healed ulcer are clinically significant.

Incompetent perforators have been demonstrated in a vast majority of the patients presenting with venous insufficiency [14, 15]

CEAP CLASSIFICATION OF THE VARICOSE VEINS	**PERCENTAGE OF THE PATIENTS WITH INCOMPETENT PERFORATORS (%)**
CLASS 3	52%
CLASS 4	83%
CLASS 5/6	90%

Relationship between the diameter of perforating veins and their correlation with the incidence of chronic venous reflux

Sl.No	PERFORATOR DIAMETER IN MILLIMETERS	INCIDENCE OF REFLUX IN PERCENTAGE OF POPULATION
1	2.0mm	10%
2	2.5mm	50%
3	3.0mm	80%
4	3.5mm	80%
5	4.0mm	88%

The number and diameter of these perforators increase with increasing severity of the disease and with the increase in chronic venous disease deterioration the diameter of these perforating veins also increase.

An incompetent perforator is characterised by high mean and peak velocity, volume flow, lower flow pulsality and venous volume displacement

Reflux of all three systems that is superficial, deep and perforators is more common in patients with chronic venous disease with skin

HISTORY OF VARICOSE VEINS:

Varicose veins were mentioned way back in 1550 B.C where it was recommended to not treat them in the “Ebers Papyrus” during the rule of Amentohep. They were also being mentioned in the ancient Greece.

During Roman times, “Celsus and Galen”, advised the use of linen bandages and plasters in the treatment of leg ulcers. Until the middle Ages, however, the philosophy of treatment of venous ulcer was formulated by Galen's “black bile theory” and his erroneous but strong views on venous blood flow. These Physicians attributed ulcers of the legs to the accumulation of black bile, menstrual blood and faeculant humours and were convinced that healing of the ulcer would be catastrophic, causing "melancholy, madness, palpitation ... and other things".

Hippocrates also recommended use of compression therapy as treatment for varicose veins

Leonardo Da Vinci in the 15th century created a few of the first true to life diagrams of varicose veins anatomy. Jeronimus Fabricius D’Aqua pendent (anatomy professor in Padova school of medicine) first described the valves in veins in 1903. Aurelius Cornelius Celsius, during the roman age performed cauterization of veins and used staggered incisions and he also proposed use of banding for leg ulcers

Ten years later Claudius Galenus using hooks stripped dilated veins between the two ligations and used wine for local application to the wounds. Hence invention of surgical ligation was attributed to him

Paulus Aegineta (607-690 A.D) student in the school of Alexandria in 7th century first reported the internal saphenous vein of the thigh.
He performed compression of vein above and below and when the vein was visible, it was marked using a special ink following which he performed the stripping of the marked vein and ligated the proximal and distal stump
Ambroise Pare (1510-1590) French surgeon also used similar techniques centuries later. William Harvey in 1628 discovered the venous valves and it role in calculation. Richard wiseman in 1676 formulated the theory of valvular incompetence resulting in dilatation of a vein.

John gay in 1868 described the changes in the post thrombotic syndrome and anatomy of the perforating veins in the ankle and coined the term venous ulcer and also proposed that ulcers can occur even in the absence of obvious varicose veins

Madelung[16] in 1885 described total removal of internal saphenous vein along with ligation of its tributaries. In 1896, William Moore in Australia performed internal saphenous vein ligation under local anaesthesia

Mayo in 1904 described a ring shaped metal instrument for stripping of internal saphenous vein. Killer in 1905 used an intravascular device consisting of a twisted metal probe which inverted the vein on pulling.

Babcock[17] in 1907 developed an "olive shaped metal probe" and used as a vein stripper, a prototype of the material used nowadays

Homan's [18,19] formulated the pathophysiology of deep vein thrombosis and recanalization with valve destructions etiology for ulcers in the affected limbs and described varicose ulcer as "poor man's disease"

Linton [20,21] in 1938 proposed varicose vein surgery on ligation of insufficient perforating veins. Linton was the first person to describe the association between venous insufficiency, communicating veins and various advanced grade of clinical presentation. The procedure that aimed at treating insufficient perforating veins in leg basically consisted of sub-aponeurotic ligation of several perforating veins through longitudinal incision in leg

The most commonly used incision were:

1. Medial incision (Linton)
2. Distal medial (Cockett)
3. Posterior incision (Felter)

In 1953 Linton began with only medial incision as most of these perforators could be reached by the medial incision. This approach required incision through the unhealthy skin for direct approach to these incompetent perforators. Linton however preferred to perform this procedure only after the ulcer had healed completely by compression therapy and bed rest as he himself noticed that the surgical incision never healed by primary union and was associated with wound infection, skin necrosis and delayed wound healing in up to 58% of cases

The cornerstone of Linton's paper was to interrupt the perforators in order to prevent the transmission of high pressures from the deep veins to the superficial veins through the perforators

Unfortunately even though this procedure was found to be very effective especially in patients with the venous ulcers in it lead to wound complications

In order to avoid complications of Linton's procedure, Cockett advised not to cleave the deep fascia which surrounds the soleal muscle because of the role of deep fascia in calf pump mechanism. Cockett not only excised the ulcer but also performed extrafascial ligation of these incompetent perforators. However, this technique was obsolete as identification of the perforator veins in the subcutaneous plane was disappointing

Dodd [22] proposed “posteromedial subfascial approach to avoid dissection of unhealthy skin”

Rob procedure [23] included use of long “stocking seam” incision for ligation of the perforating veins. Finally De Palma [24] in 1974 formulated a modified operative approach wherein multiple small parallel skin incisions made along the natural skin lines over the medial aspect and recommended subfascial as well as subcutaneous division

Negus and Frudgood [25] showed “84%healing rate after subfascial ligation of incompetent perforators using Linton and Dodd approach performed on 109 ulcerated lower limbs”

Since Linton’s technique was abandoned by many vascular surgery, later on a group German authors by name Hauer [26] showed the use and feasibility of an endoscopic approach for ligating the perforator veins subfascially. The rationale behind this approach was that it was based on the possibility of creating a “virtual space” below the deep fascia using laparoscopic instruments. One another advantage of this technique was that it offered the possibility of avoiding further damage to an already scarred tissue around the site of ulcer and decrease the possibility of wound infection or complications that affected Linton’s technique

A group of vascular surgeons in united states decided to collect the experience of seventeen centres in a registry known as "North American subfascial endoscopic perforator ligation surgery [27]". The data collected not only confirmed it's feasibility but also the safety of this technique i.e., no death or thromboembolism with faster rates of ulcer healing

The procedure was done in 158 patients , 90% of the patients who had leg ulcers treated with subfascial endoscopic perforator ligation healed and required an average of 38 days to completely heal when compared to patient subjected to conservative treatment and a mean ulcer healing rate of 66%. This procedure required a short hospital stay of less than 24 hours in 66% of the cases. This technique was also cost effective when compared to the cost effectiveness of conservative management. Though this trial was not a randomized one, the ulcers failed to heal in 101 patients until surgery was performed

The first randomized trial carried out by Pierik [28] enrolled "40 patients with active ulcers and the interim analysis of which showed statistically significant difference between the two groups with no complication in SEPS group versus ten in the Linton's group"

A number of attempts are made to interrupt the incompetent perforators avoiding the long incisions through the compromised, lipodermatosclerotic skin which

have a poor heling properties. Albanese [29] in 1965 proposed a new approach in which he developed a new cutting instrument later modified by Edwards named as the "Phlebotome". This instrument was inserted under the deep fascia away from the lipodermatosclerosis or the ulcer site and performed shearing of all visualised perforators. Edwards [30] treated 24 patients using this technique and found none post-operative complications. The disadvantages of this technique is that it was a blind insertion of the instrument in the space below deep fascia and led to painful subfascial haematoma and in elderly women with friable skin can lead to skin necrosis. Hence a combination of ligation under visualization along with Edward's proposal of insertion site led to development of an endoscopic approach for perforator surgery.

The first attempt was made using a "Laryngoscope" where in the straight blades were passed below the deep fascia and fascia was lifted up away from the muscle through a small calf incision suggested by David Negus [31]. Elevation of deep fascia with laryngoscope with illumination led to the visualization of the incompetent perforating veins which were clipped using long applicators. Disadvantage of this technique was inadequate visualization of the subfascial space.

Conrad in Australia and Gloviczki [32] in USA proposed "carbon di-oxide insufflation technique which led to a wide subfascial space "cake view" through which interruption of perforators can be accomplished"

Jugenheimer and Junginger [33] reported “subfascial sectioning of incompetent perforators in 103 legs with primary varicose veins. Post-operative wound healing delay was seen in 2.9% of patients and 2% developed dysesthesia in the distribution of sural nerve with other rare complications of subfascial haematoma and dysesthesia in the area of saphenous nerve. After 27 months of follow-up, 1.9% patients had a persistent incompetent perforators or newly formed perforators”

Wittens et al [34] described “severe subfascial infection in 1 patient in both legs requiring surgical intervention”. Meta-analysis by Tenbrook [35] and co-workers pooled data from 20 published series including 1140 limbs who underwent surgical treatment demonstrated “ulcer healing in 88% treated with SEPS with or without superficial venous ablation and a recurrence rate of 13% for a follow up period of 24 months. 40% healed in 30 days, 64%healed in 60 days and 86% healed after 60 days”

O’donnell [36] reviewed with 22 series of SEPS observed “90% healing rates over 21 months”. He used irrigation of ringer lactate solution in subfascial space for liquid distension.

Uncu et al [37] reviewed his series of 28 patients observed “a significant statistical improvement in symptoms after 3 months by chronic venous insufficiency index”

Gerhard Sattler refined his endoscopic technique by introducing angulated optics using camera at 45 degree angle

S. Subromonia et al performed an extensive research In 2007 for treatment for varicose veins and particularly emphasized on articles published in last 10 years, concluded that "the treatment of varicose veins which is aimed at removing long reflux segments and venous reflux can be achieved through Endovenous ablation or the usual conventional surgery"

Proebstle and Heedemann et al have reported "performance of SEPS under local anaesthesia using tumescent successfully in 78%of the patients". The presence of deep venous incompetence in non-healing ulcers or recurrent ulcer was not an identifiable cause

Kalea et al [39] for mayo clinic examined results in specifically in post thrombotic patients. The study observed that "the 5 yrs, ulcer recurrence was higher in the subgroup of post thrombotic patients but they still had a clinical benefit of a better venous severity score and a better ease of treating the superficial ulcers with their pre-operative state"

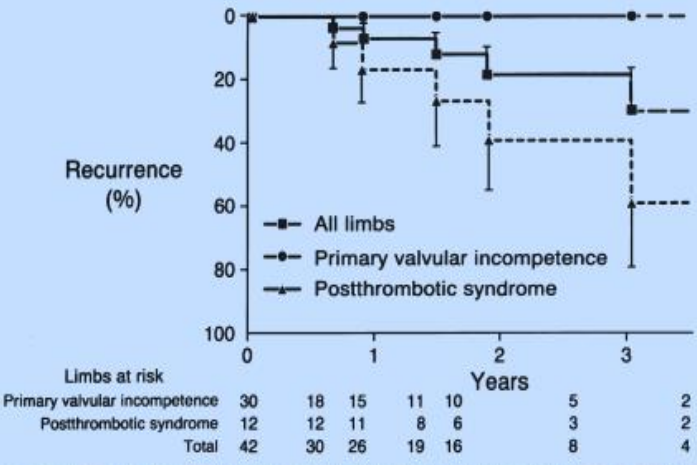


Figure 4 Cumulative ulcer recurrence by Kaplan–Meier life-table analysis in 42 limbs with Class 5 and Class 6 disease prior to SEPS. Subgroup analysis was performed for limbs with primary valvular incompetence ($n = 30$) and those with post-thrombotic syndrome ($n = 12$; $p < 0.05$). The dashed line in each curve represents the point at which the SEM exceeded 10%. (Reproduced from ref. 38 with permission from Excerpta Medica Inc.)

Schanzer and pierce et al have documented "haemodynamic improvements in 22 patients who underwent treated for isolated perforator interruption". In 1992 the results were confirmed by Padberg [41] and colleagues who used an air plethysmographic study based on foot volumetry and duplex scanning. "In patients with no ulcer recurrence, the half refilling time and expulsion fraction both improved significantly". They used a strain gauge plethysmography to quantitate venous incompetence and calf muscle pump function before and after subfascial endoscopic perforator ligation surgery. "Significant improvement observed in 31 limbs studied for 6 months after SEPS. 7 limbs undergoing SEPS alone had significant clinical improvement"

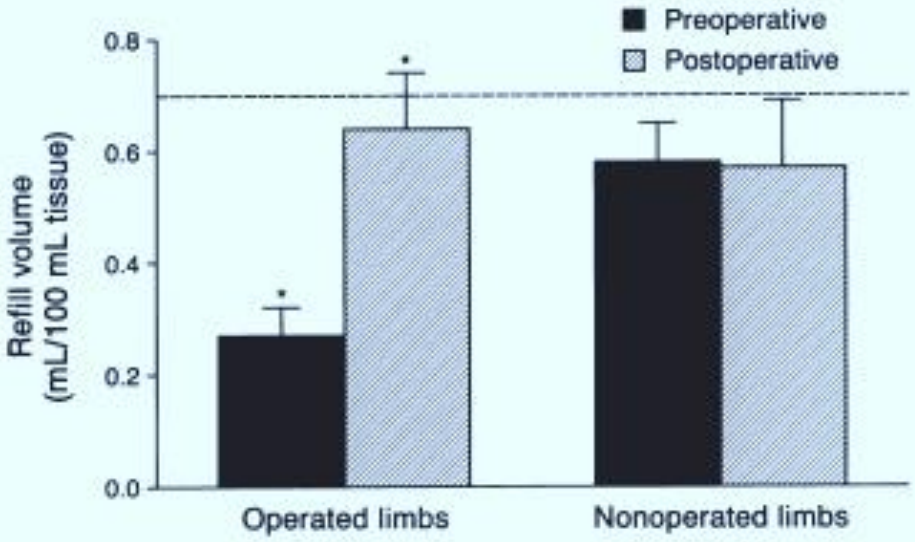


Figure 8 Calf muscle pump function (refill volume) measured both pre- and postoperatively in the operated ($n = 28$) and non-operated contralateral limbs ($n = 18$). *$p < 0.01$; dashed line indicates normal refill volume ≥0.7 ml/100 ml tissue. (Reproduced with permission from ref. 24.)

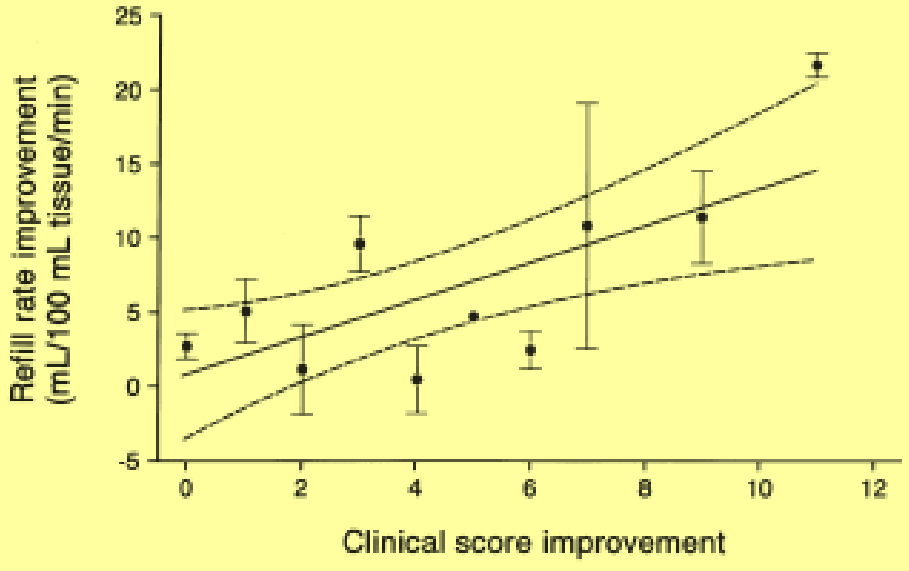


Figure 9 Correlation between clinical and hemodynamic improvement (measured by refill rate) in 29 limbs following SEPS, with or without correction of superficial reflux. The mean values ± SEM and the results of linear regression analysis are depicted with 95% confidence intervals ($r = 0.77$, $p < 0.01$).

Baron et al [38] reported “decrease in edema, regression of changes, and subjective improvement in the physical performance in the patients in the study”. Out of 53 limbs with venous ulceration, primary healing of ulcers occurred in 41 within 12 weeks following the SEPS. In the remaining 12 cases, healing of these ulcers took longer time, but none exceeded 6 months

Nelzen et al [40] reported a “wound complication rate of 16 % in a study performed on 37 patients and ulcer healing was 100 % in their cases”. Luebke and Brunkwall [42] also reported “significant lower rate of wound infection with SEPS and concluded that his procedure benefits most patients of chronic venous insufficiency”. Kurdal et al [43]also achieved “sustainable wound healing with SEPS”

Thousand patients between 1961-1971 underwent subfascial endoscopic perforator ligation showed an overall recurrence rate of 10%. A review of the most recent ten reports on SEPS reported 15%recurrence rate in 767 patients

The safety of subfascial endoscopic perforator ligation was confirmed in the North American SEPS (NASEPS) Registry. In which the most recent report, 40 of 146 operations were included with an average 24 months of follow up.

Wound complications had occurred in 6% and deep vein thrombosis in one patient at 2 months post-surgery.

Cumulative ulcer healing rate at 1 year was 88%, and a median time to healing of 54 days .Ulcer recurrence was 16% at 1 year and 28% at 2years

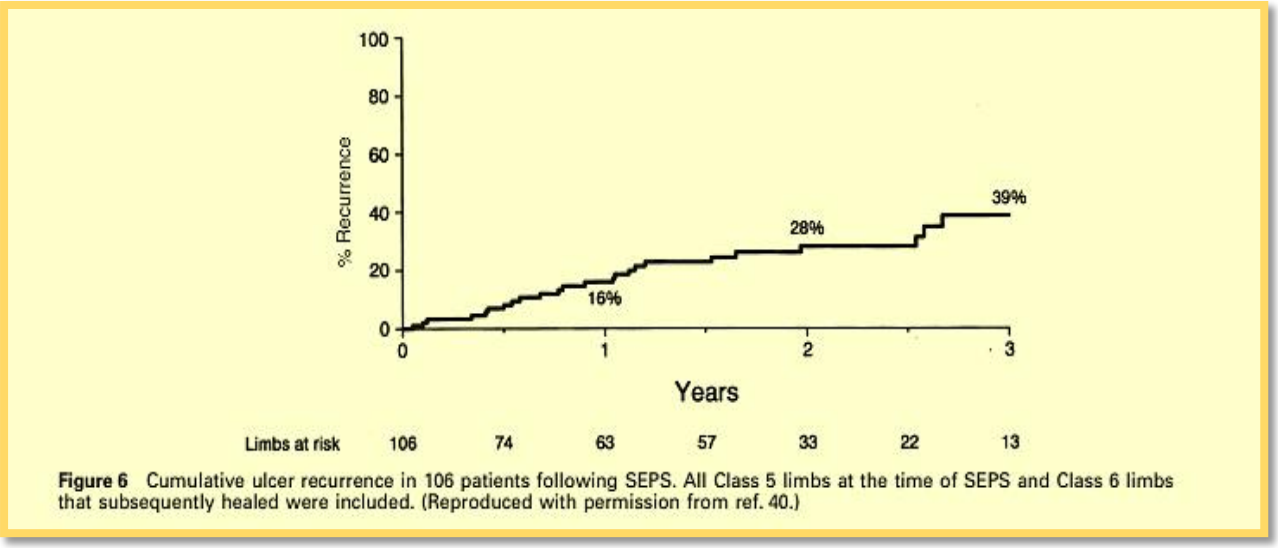


Figure 6 Cumulative ulcer recurrence in 106 patients following SEPS. All Class 5 limbs at the time of SEPS and Class 6 limbs that subsequently healed were included. (Reproduced with permission from ref. 40.)

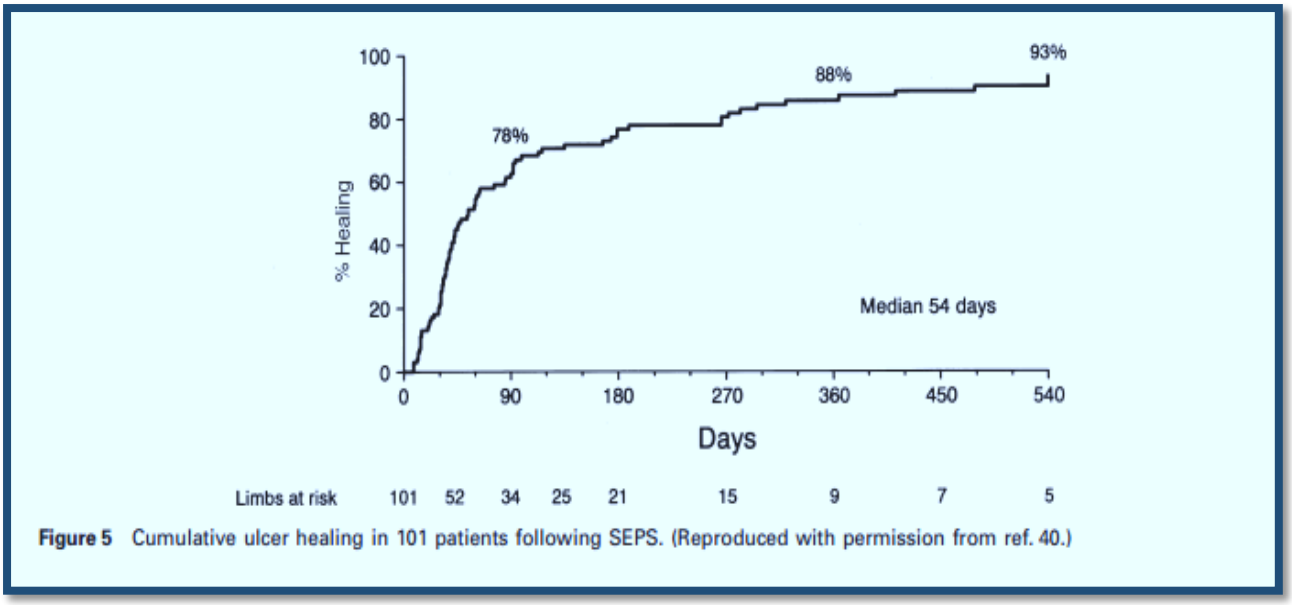


Figure 5 Cumulative ulcer healing in 101 patients following SEPS. (Reproduced with permission from ref. 40.)

Post-thrombotic limbs had responded worse than limbs which had primary valvular incompetence.

Post-thrombotic patients had recurrence rate of 26% at 2 years versus the recurrence rate of those patients with primary valvular incompetence was 20% at 2 years. Totally 122 patients had active or healed ulcers pre-operatively and 23% of these (28 patients) had recurrent or new ulcers at the final follow-up. Although the recurrence rates was high, they were still comparable favourably to results of non-operative management

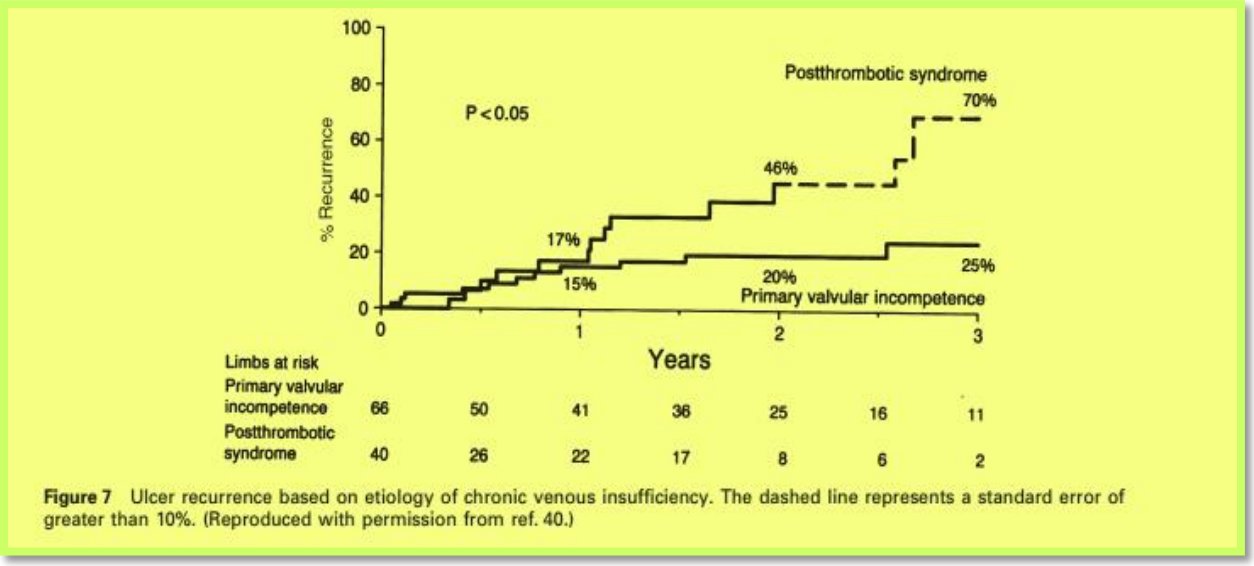


Figure 7 Ulcer recurrence based on etiology of chronic venous insufficiency. The dashed line represents a standard error of greater than 10%. (Reproduced with permission from ref. 40.)

In addition to ulcer healing, significant clinical improvement was also documented using a scoring system even in patients who had ulcer recurrence or had new ulcers.

It was observed that pain was less severe and the size of the recurrent or new ulcers became smaller, allowing better management with reduced disability. Data from other centers regarding the results of SEPS have been accumulating, but the mean follow up in these studies have not been beyond 2 years duration

An important large randomised controlled trial (level I), the Dutch ulcer trial, was based on 200 C6 limbs, which were randomized into treatment with elastic compression alone or SEPS (with or without GSV treatment) with elastic compression "This trial focused on the effect of SEPS on ulcer healing or recurrence, was performed in 12 centers with the ulcer-free period, was determined by Kaplan-Meier analysis which was the primary outcome. The secondary endpoints were ulcer healing, recurrence, quality of life (QOL), and cost-effectiveness of the treatment performed". The investigators stratified patients into:

(1) New or recurrent ulcer

(2) Presence of deep venous reflux

(3) The specific center where the treatment (medical or surgical) was done

Concomitant superficial venous surgery of the Great saphenous vein or short saphenous vein was performed in 54% of the patients and in addition 40 patients had previous treatment of GSV,hence only 6% of patients apparently had treatment of incompetent perforators alone. Thus, it is impossible to separate if the effect is due to treatment of the GSV and incompetent perforators from treating the incompetent perforators alone. "Over a median follow-up length of 27 months, the ulcer-free

period was comparable between the SEPS group (72%) and the compression group (53%), as were ulcer recurrence (22%) and ulcer healing (83%)".

In a study done by hammasten group measured the diameter of long saphenous vein at four levels after ligating the incompetent saphano-femoral junction and incompetent perforators and "it was found that the diameter of long saphenous vein reduced by 40%".

Definition of an outcome and assessment of the efficacy require a thorough understanding of the disease and its complications and a therapeutic goal that can be measured objectively. Padberg [48] had studied outcome reporting extensively and in his recent article he states that 'everyone will benefit from an integrated assessment of symptoms, clinical findings, non-invasive examinations and functional outcomes to better define the role of surgical, physical and medical therapies for chronic venous disease'.

The CEAP classification was formulated as a common descriptive platform for reporting of diagnostic information in chronic venous disease. Eklof et al [49,50] reported that the CEAP classification was designed as a tool for regular patient documentation and management. The clinical component scored from 0 to 6 indicates increasing disease severity, ranging from none (0 points) to active ulcers (6 points). The aetiological component is used to denote if the venous disease is congenital, primary or secondary in nature. The anatomical classification denotes if the veins involved as superficial, deep or perforating. The pathophysiological classification identify the presence or absence of reflux in the superficial, communicating, or deep systems, as well as the existence of any outflow obstruction.

The primary drawback in using the CEAP classification is it is physician-generated disease assessment. This is especially true for clinical C4 and C5 disease. The static nature of these measurements makes it very difficult for a physician to track the changes over time in response to therapy.

Early studies regarding the CEAP classification noted a relationship between results in the CEAP scores and other outcome assessments, including Physician and patient-centred instruments. In a study among patients with deep venous reflux, Gillett et al [52] noted that ‘a significant increase in the Venous Clinical Severity Score (VCSS) and Venous Segmental Disease Score (VSDS) paralleled CEAP clinical class’.Kahn et al [51] in a study relating clinical classification of venous disease with patient-related quality of life found that ‘clinically assessed CEAP class was significantly associated with generic and venous disease-specific quality of life. Ricci et al. noted that the ‘CEAP classification and VCSS had equally high negative predictive values’. To increase sensitivity to the changes that occur during the course of therapy and to encourage wider use as a clinical assessment instrument, the CEAP classification underwent a revision in 2004. The framework of the CEAP system was maintained, but several categories were expanded and refined to enhance the dynamic response to therapy. These included a change in the C classification which divided the C4 class into ‘a’ and ‘b’ categories that can predict the risk of ulceration based on the type of skin changes seen, as well as refinements of the E, A and P classifications to include the use of the descriptor ‘n’ in order to indicate no venous abnormality. In addition, a basic CEAP system was introduced using the highest descriptive element for clinical

classification. This made the clinical CEAP system more attractive to the clinician for regular use. An advanced CEAP classification, including all parameters, was made available for standardised reporting and research.

Although the CEAP classification is been proven to be a useful descriptive instrument in classifying venous conditions, extra information is needed regarding disease severity and longitudinal changes and improvement in patient conditions during treatment. In regard to this need for a disease severity measurement, "the American Venous Forum" in 2000 derived the Venous Severity Scoring (VSS) system from elements of the CEAP classification.

The VSS system is an evaluative instrument. It was designed to supplement the CEAP system and provide a method for serial assessment. It is been proven to weather intra-observer and inter-observer variability. The basic components of the system are easy to apply and to learn. The features of the VSS are critically needed for longitudinal follow-up of a patient's clinical condition during and following an intervention. There are three components of this new scoring system.

First: The venous disability score

Second: The venous segmental severity score

Last: The venous clinical severity score

The study by Masuda et al. on incompetent perforating veins which were treated with sclerotherapy examined the effect of this treatment on scoring systems like the VCSS and the VDS. During the study period of four years, "80 limbs demonstrating

incompetent perforators were treated with ultrasound guided sclerotherapy". Patients were scored using the CEAP classification, VCSS and VDS before the treatment, and reassessed in less than one month after the procedure, and at three- to six month intervals for about five years after therapy. On the pre-treatment CEAP classification, 76% of all participants were C4, with 46% being C6. There were no C0 or C1 scores and all patients reported significant pain at the site of the perforator.

The pre-treatment median VCSS was 8 and the median VDS was 4. At the initial post-treatment visit, the median VCSS had reduced to 2 and the median VDS reduced to 1. Following perforator sclerotherapy, CEAP C4 and C6 patients demonstrated significant improvement. This study demonstrated "the meaningful application of VCSS and VDS, as well as the correlation between the two scoring systems in terms of demonstrating significance". The analysis of the CEAP scores further also demonstrated the usefulness of combining these instruments in evaluating the outcome of therapy.

Meissner et al. have evaluated the validity of the VCSS in a 2002 study involving 128 limbs. Patients with known chronic venous disease were scored for pain, varicose veins, presence/absence of oedema, skin pigmentation, inflammation, induration, use of compression therapy and the presence, duration and size of ulcers. Limbs were scored twice by the same observer and again by another second observer. On the CEAP classification, classes C2– C6 were represented and class C1 was excluded from the study. The VCSS

Scores were recorded for each observer and were used to evaluate if there was any interobserver and intraobserver variability. The results of this study had demonstrated that “the VCSS is a valid measurement tool, the scores of which increases as the CEAP clinical class increases”. Reliability of the VCSS system was confirmed by the results obtained from the observer variability measures. There was no much difference in limbs scored by the same observer during the first 28 days, and interobserver reliability was good, even though there were significant differences between observers. The areas of interobserver difference were pain scores, skin pigmentation measures and inflammation

REVISED VENOUS CLINICAL SEVERITY SCORING SYSTEM (2014)

	None: 0	*Mild: 1*	*Moderate: 2*	*Severe: 3*
Pain or other discomfort (i.e, aching, heaviness, fatigue, soreness, burning) Presumes venous origin		Occasional pain or other discomfort (ie, not restricting regular daily activities)	Daily pain or other discomfort (ie, interfering with but not preventing regular daily activities)	Daily pain or discomfort (ie, limits most regular daily activities)
Varicose veins "Varicose" veins must be 3 mm in diameter to qualify in the standing position.		Few: scattered (ie, isolated branch varicosities or clusters) Also includes corona phlebectatica (ankle flare)	Confined to calf or thigh	Involves calf and thigh
Venous Oedema Presumes venous origin		Limited to foot and ankle area	Extends above ankle but below knee	Extends to knee and above
Skin pigmentation Presumes venous origin Does not include focal pigmentation over varicose veins or pigmentation due to other chronic diseases	None or focal	Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of Calf
Inflammation More than just recent pigmentation (ie, erythema, cellulitis, venous eczema, dermatitis)		Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of Calf

Induration **Presumes venous origin of secondary skin and subcutaneous changes (ie, chronic oedema with fibrosis, hypodermitis). Includes white atrophy and lipodermatosclerosis**		Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of Calf
Active ulcer number	0	1	2	3
Active ulcer duration (longest active)	N/A	3 months	3 months- 1 year	Not healed for 1 year
Active ulcer size (largest active)	N/A	Diameter 2 cm	Diameter 2-6 cm	Diameter 6 cm
Use of compression therapy	0 Not used	1 Intermittent use of stockings	2 Wears stockings most days	3 Full compliance:

CLINICAL RESULTS OF SUBFASCIAL ENDOSCOPIC PERFORATOR SURGERY

Author and year	No of limbs treated	No of limbs with active ulcer	Concomitant saphenous ablation done (%)	Wound complications post operatively (%)	Ulcer healing observed (%)	Ulcer recurrence on follow up	Follow up duration Months
Jugenheimer and Juginger Yr:1992	103	17	97(94)	3(3)	16(94)	0	27
Pierek et al Yr:1995	40	16	4(10)	3(8)	16(100)	1	46
Bergan et al Yr:1996	31	15	31(100)	3(10)	15(100)	0	12-24
Wolter's et al Yr:1996	27	27	0(0)	2(7)	26(96)	2(8)	12-24
Padberg et al Yr:1996	11	0	11(100)	--	+	0	16
Pierek et al Yr:1997	20	20	14(70)	0(0)	17(85)	0(0)	21
Gloviczki et al Yr:1999	146	101	86(59)	9(6)	85(84)	26(21)	24
Llig at al	30	19	-	-	17(89)	4(15)	9

Yr:1999							
Suto et al Yr:1999	27	20	17(63)	2(7)	18(90)	5(25)	8
Nelzen et al Yr:2001	149	36	132(89)	11(7)	32(89)	3(5)	32
Kalea et al yr:2002	103	42	74(72)	7(6)	38(90)	15(21)	40
Larati et al Yr:2004	51	29	33(65)	3(6)	22(76)	6(13)	38
Baron et al	98	53	36(42)	-	53(1000)	0(0)	-
Total no of limbs(%)	836(100)	395(47)	537/739 (68%)	50/680 (7%)	355/395 (90%)	62/580 (11%)	

GUIDELINES OF THE AMERICAN VENOUS FORUM FOR MANAGEMENT OF INCOMPETENT PERFORATOR VEINS WITH OPEN OR ENDOSCOPIC APPROACH (2011)[44,45,46,47]

NO	Guidelines	Grade of recommendation 1- We recommend 2- We suggest	Grade of evidence A-high grade B-moderate grade C-low grade
4.20.1	For open surgical treatment we no longer recommend open Linton's technique owing to associated morbidities	1	A
4.20.2	We suggest perforator incompetence treatment in patients with advanced venous disease to improve venous haemodynamics and clinical outcomes	2	B
4.20.3	We suggest perforator interruption in patients with primary valvular incompetence and less so in post thrombotic limbs	2	B

MATERIALS AND METHODS

TYPE OF STUDY: This is a prospective longitudinal clinical study

SIZE OF THE STUDY: 30 patients selected by systematic sampling method

DURATION OF THE STUDY: November 2014 to September 2015

PLACE OF STUDY: Department of general surgery

Government Kilpauk Medical College and Hospital

INCLUSION CRITERIA:

- Patient presenting with various degrees of chronic venous insufficiency CEAP class 4 to class 6
- Patients with duplex study suggestive of perforator incompetence
- Patient of both sexes
- Age from 18 years to 60 years
- Patients who are willing to give consent for study will be included

EXCLUSION CRITERIA:

- Patients with Recurrent varicose veins
- Deep venous reflux
- Deep venous thrombosis
- Saphenopopliteal reflux
- Arterial occlusive disease
- A previous lower limb surgery.

- Pregnancy

SAMPLE SIZE – sample of 30 CASES

DATA COLLECTION:

- 30 eligible patients are chosen with the clinical diagnosis of varicose veins
- One limb with perforator incompetence was considered as one case
- History and signs are recorded.
- Basic routine investigations were done for all patients
- CEAP classification category will be determined
- Duplex study
- Venous disability score preoperatively and reassessed post-operatively
- Venous clinical severity scoring preoperatively and reassessed post-operatively

- Ulcers and their size will be noted pre-operatively and reassessed post-operatively
- Consent will be obtained for inclusion under study for surgery

SURGICAL TECHNIQUE:

PREOPERATIVE PREPARATION:

Pre-operative evaluation included duplex scanning of the affected limb and the incompetence in superficial, deep and perforator levels were documented. The incompetent perforator vein on the skin was marked accurately using a skin marker on the day of surgery using doppler which helps the surgeon during surgery. All patients received a single dose prophylactic antibiotic just before induction of anaesthesia for patient with active ulcers

OPERATIVE TECHNIQUE:

The procedure of SEPS was performed under spinal anaesthesia. Patient in supine position and in Trendelenberg position with flexion and abduction and at hip and flexion at knee. In our study this technique was performed using two port technique. We did not use the tourniquet during the surgery. Limb was painted and draped. A skin incision was made measuring 13 mm one hand breadth or 5 cm below and medial to tibial tuberosity and was deepened in layers. Skin retractors applied for better visualization .The deep fascia was identified and incised.

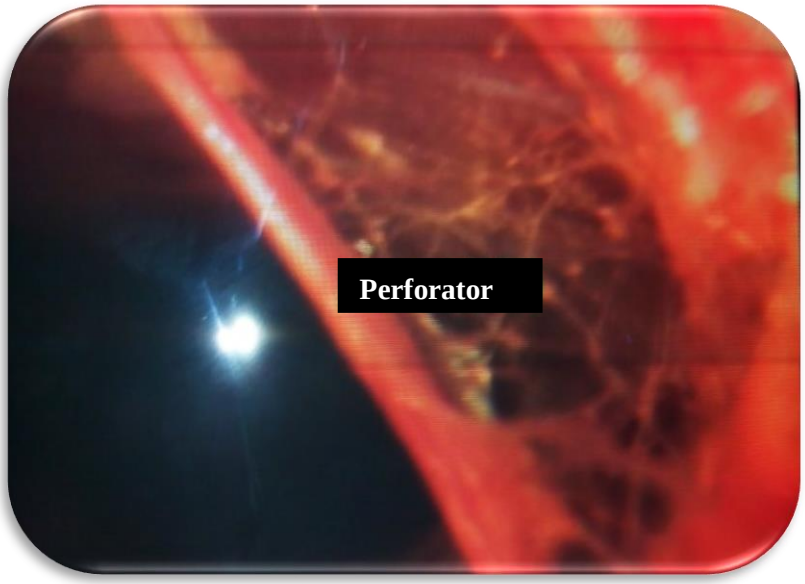
Port site incision

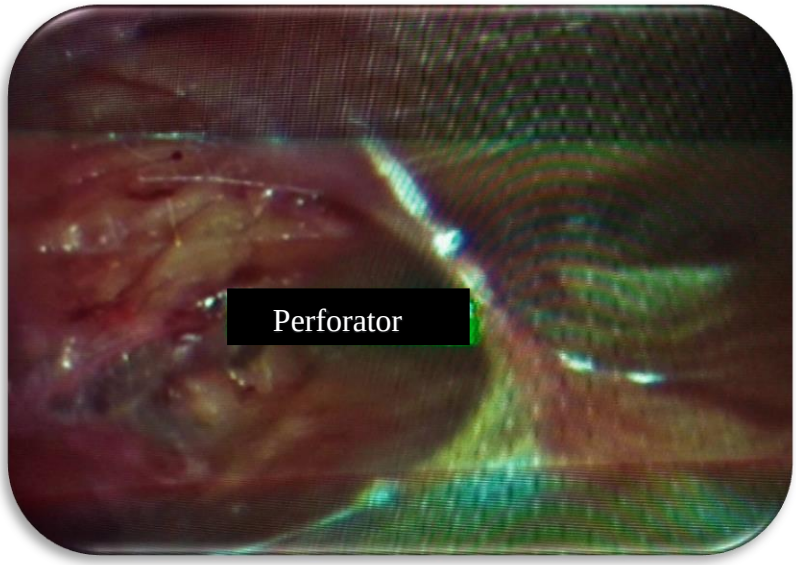
A 10mm trocar inserted through which a 0 degree telescope and light source connected was inserted through 10mm port. Carbon-di-oxide insufflation done and using the telescope a subfascial space was created with the instrument directing towards the medial malleolus. The insufflator pressure was maintained at 15mm Hg and the subfascial space visualized. Under direct telescopic guidance another 5mm working port incision made 5cm below and medial to the previous incision.

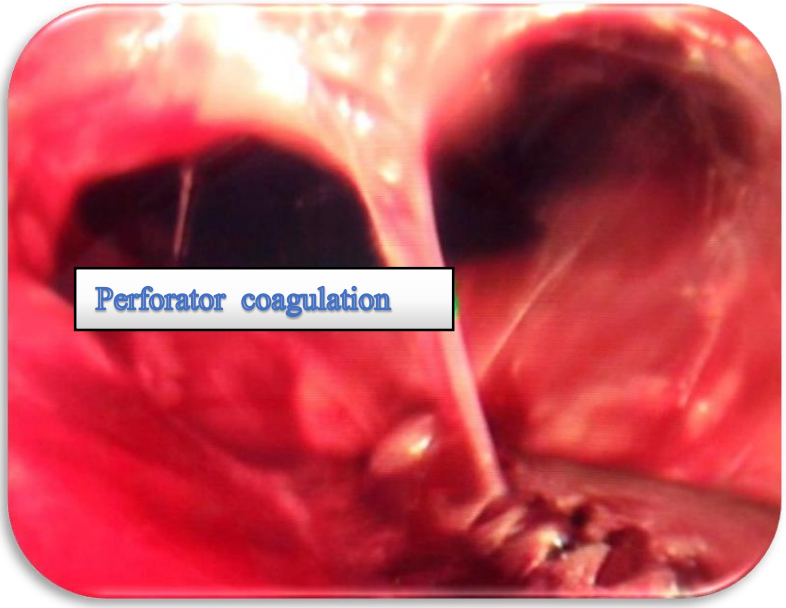
A bipolar cautery inserted through the working port. The large perforating veins bridging from the underlying gastrocnemius muscle to the fascia above were coagulated using bipolar cautery and with the help of endo-scissors divided. This subfascial space was opened by blunt dissection from the shin of tibia to upto midline of posterior aspect of limb and distally up to about 2-3cms above medial malleolus. After completing the procedure, the instruments and ports were removed and carbon dioxide was manually expressed out. The skin incision were closed and the limb was elevated and an elasto-crepe bandage bandage applied.

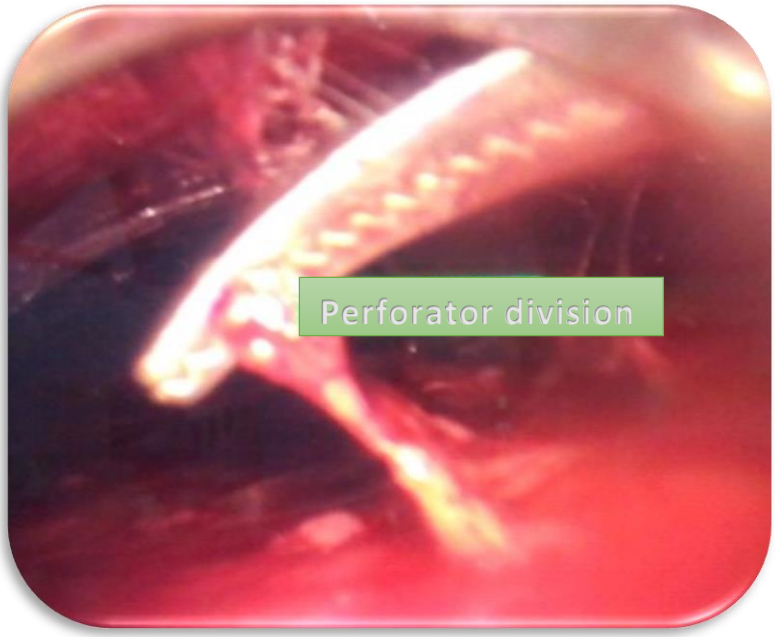
Telescope and working port site over the limb

with dissection upto just above medial malleolus


Perforator


Perforator


Perforator coagulation

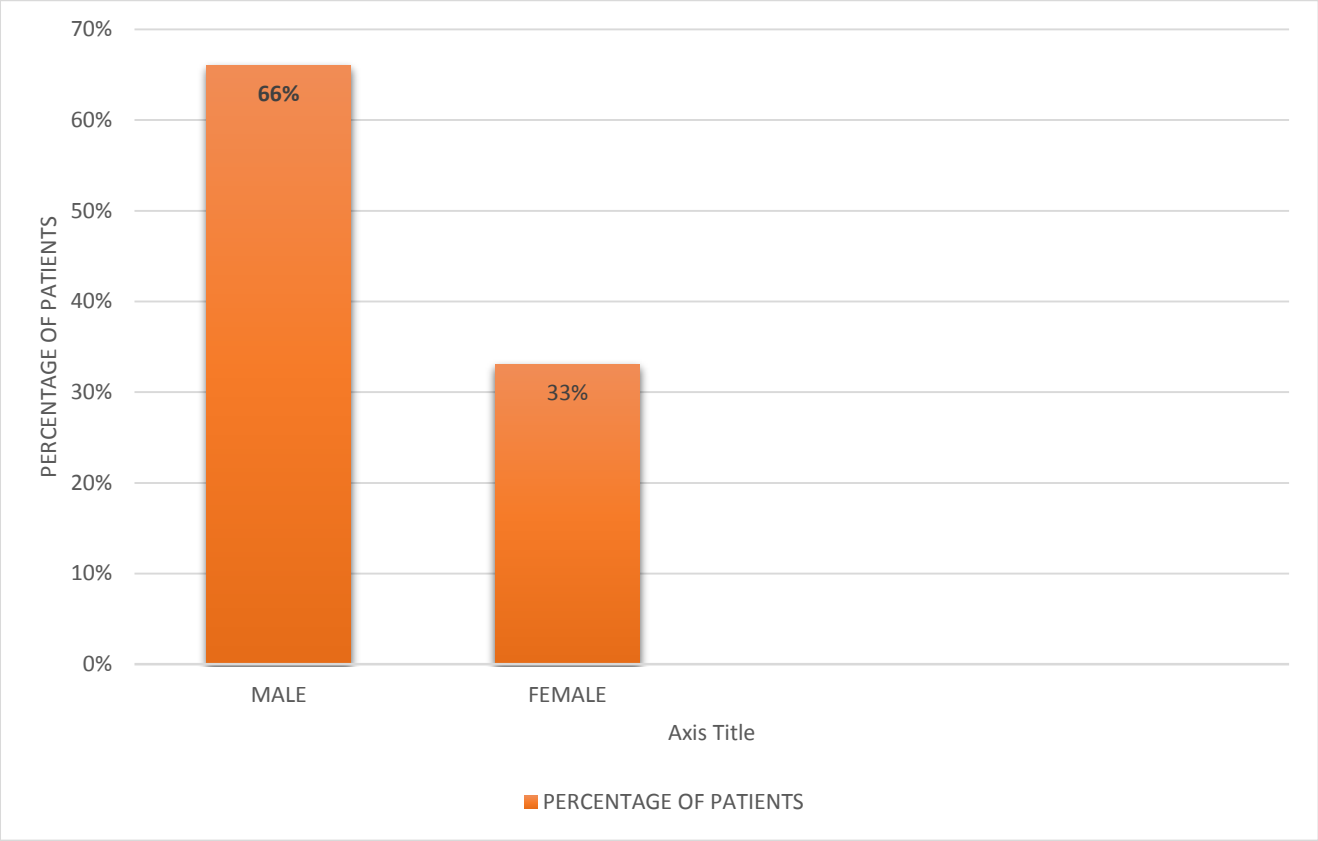

Perforator division

Post-operative assessment:

Once the spinal anaesthesia wears off, the patients were encouraged to ambulate on the same day as surgery and all patients received antibiotics for 48 hours post-surgery. Patients were discharged in 3-6 days with post-operative instructions on ambulation, limb elevation and maintaining the elasto-crepe compression bandage regularly. Ulcer dressings were done regularly and skin sutures removed on follow up with assessment of clinical symptom reduction and ulcer size reduction at 1 ,2 and 3rd week post-surgery.

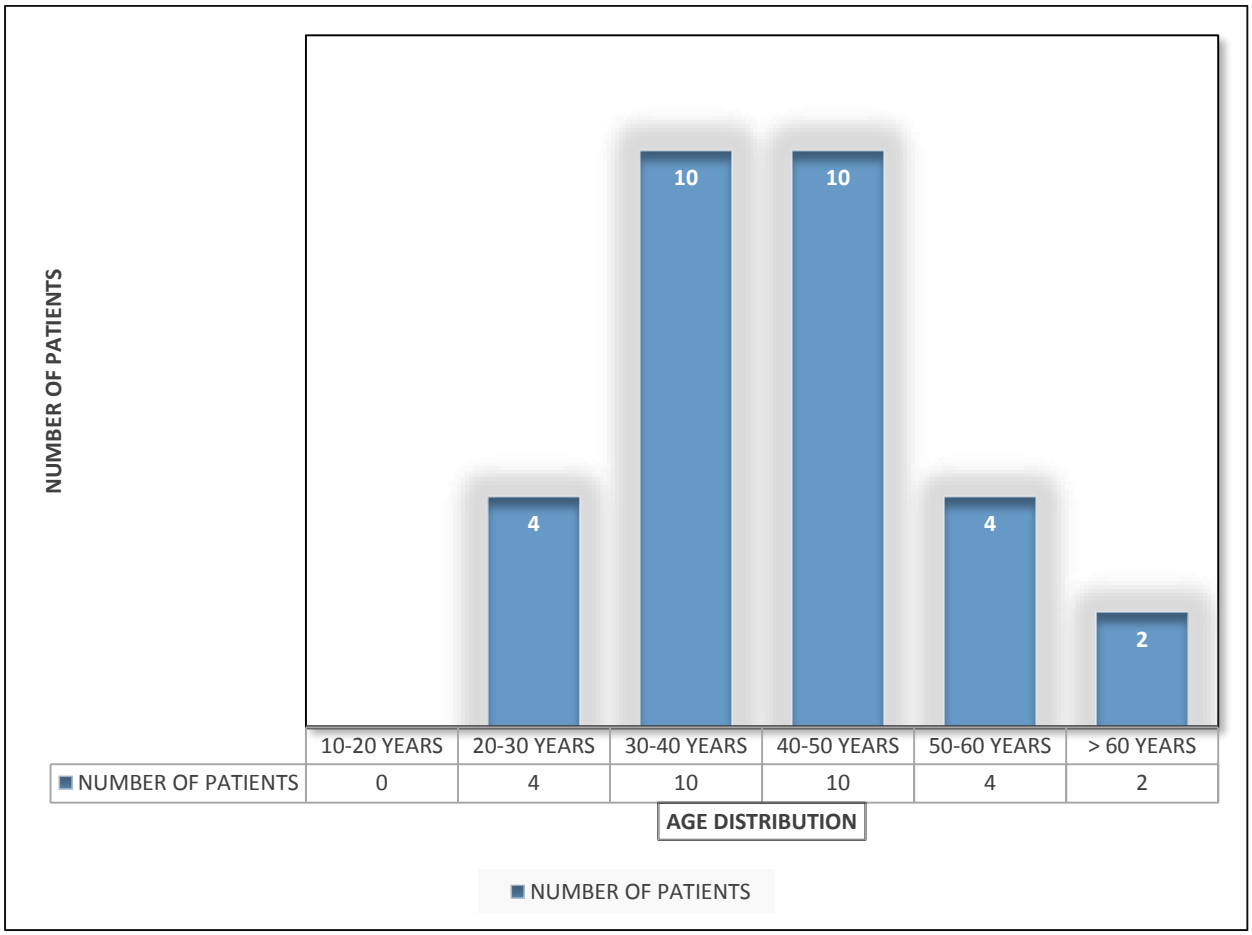
SEX DISTRIBUTION OF PATIENTS PRESENTING WITH PERFORATOR INCOMEPTENCE INCLUDED IN THE STUDY

CHART NUMBER 1



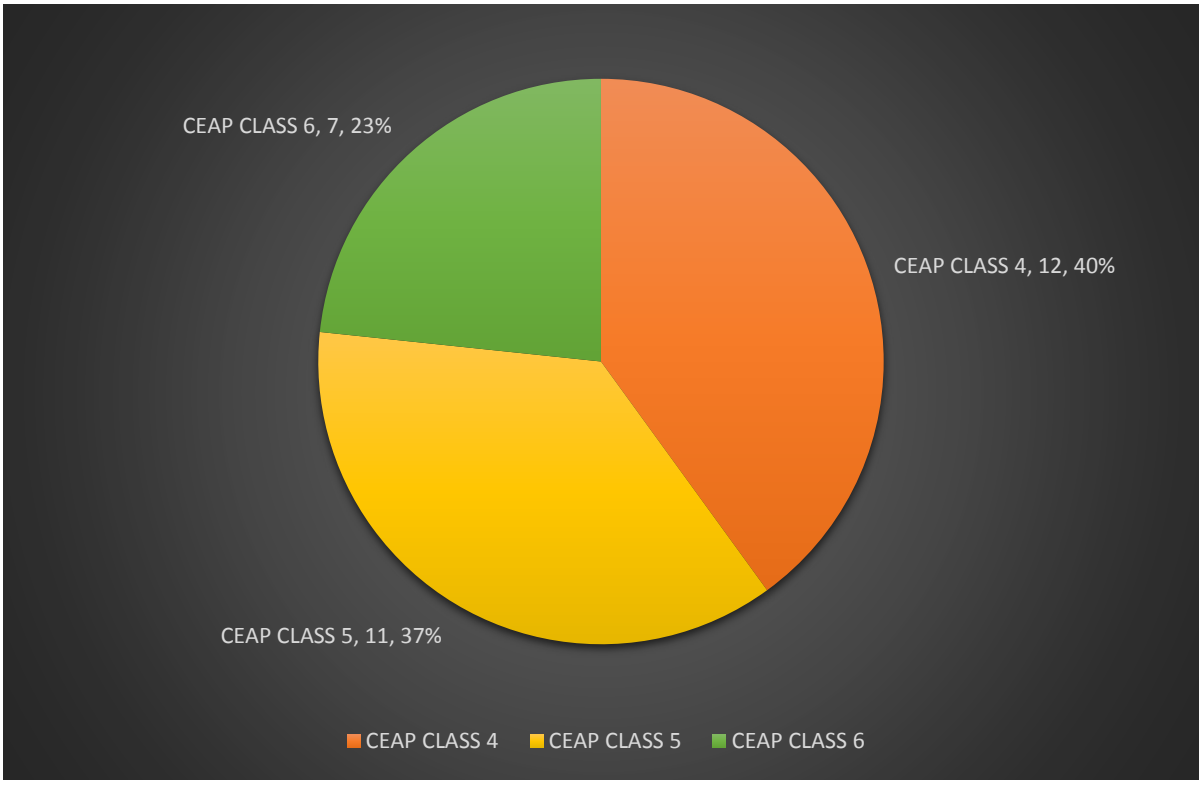
AGE DISTRIBUTION OF PATIENTS PRESENTING WITH PERFORATOR INCOMPETENCE UNDERGOING SUBFASCIAL ENDOSCOPIC PERFORTOR LIGATION SURGERY

CHART NUMBER 2

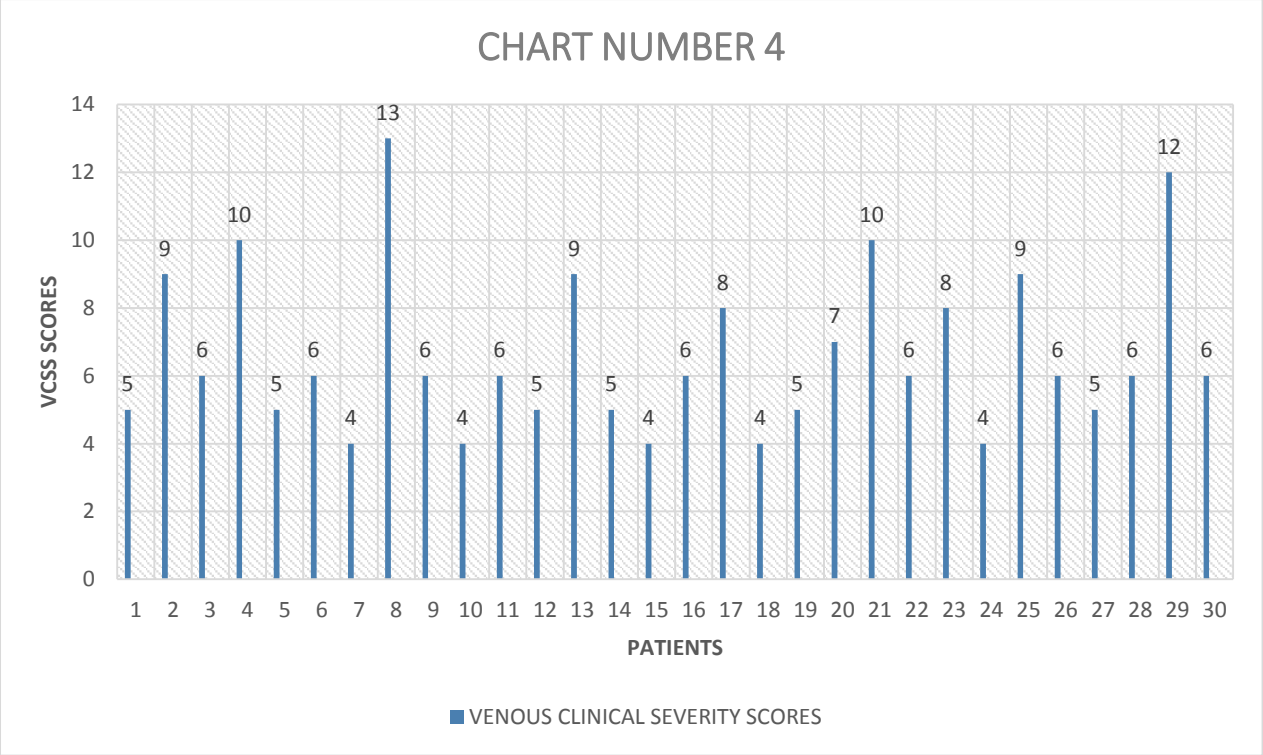


DISTRIBUTION OF PATIENTS WITH REGARD TO CEAP CLASSIFICATION OF VARICOSE VEINS

CHART NUMBER 3

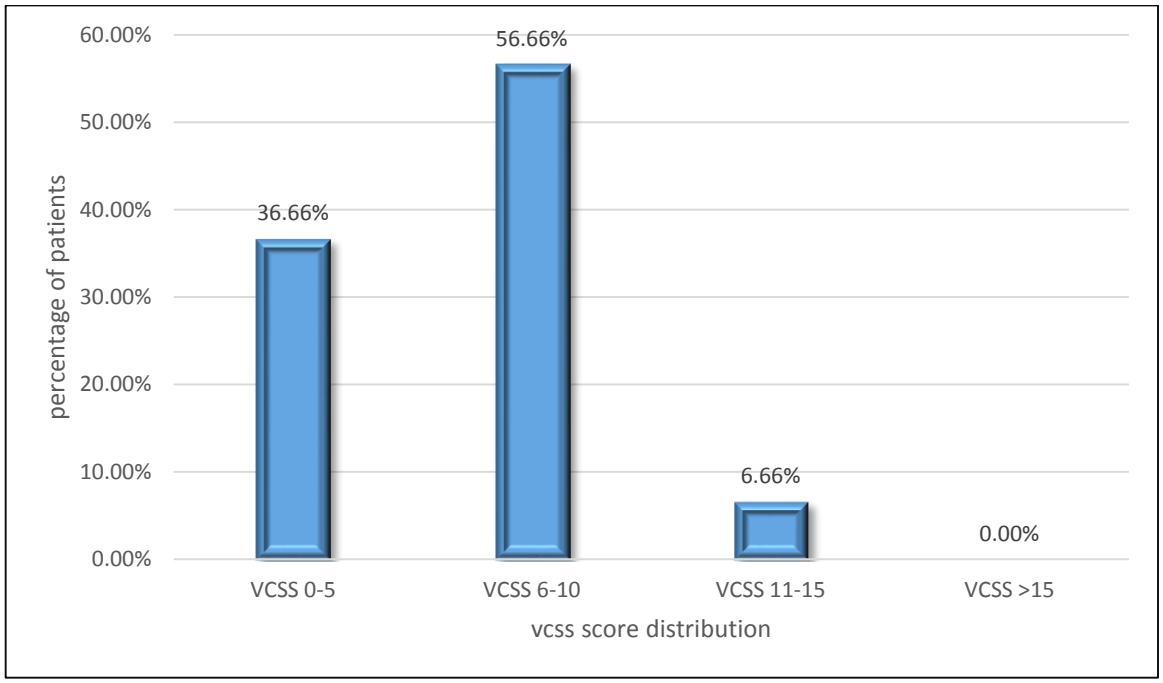


VENOUS CLINICAL SEVERITY SCORES OF PATIENTS PRIOR TO SURGERY FOR PERFORATOR INCOMPETENCE

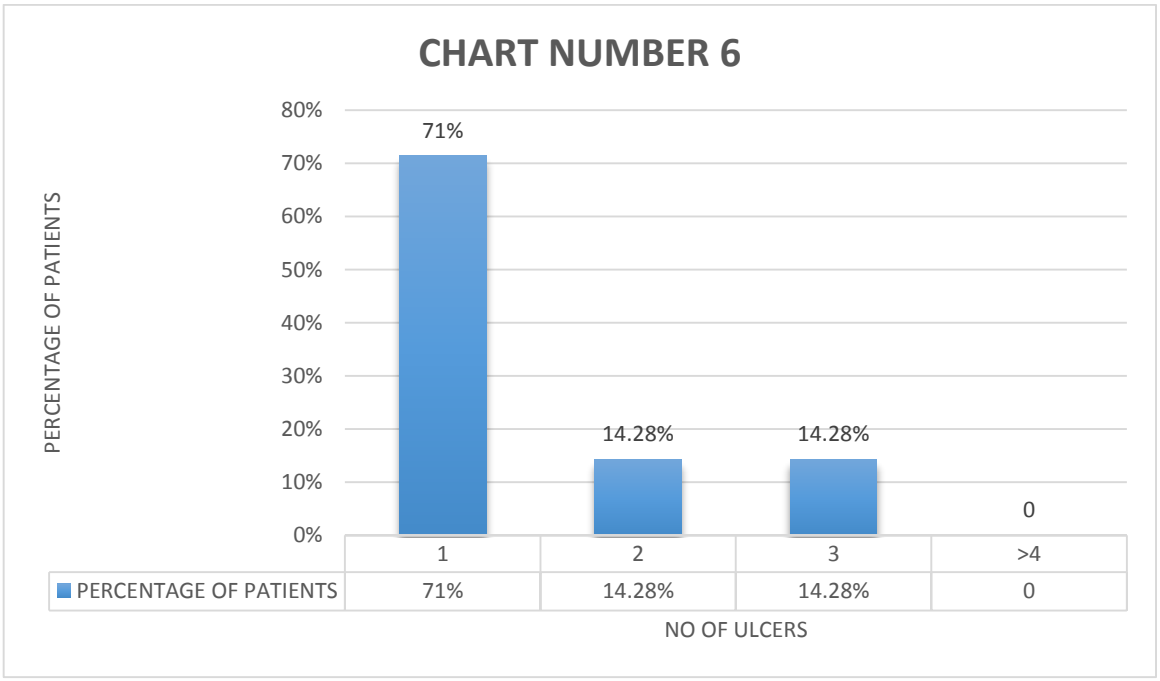


PERCENTAGE OF PATIENTS PRESENTING WITH PERFORATOR INCOMPETENCE IN DIFFERENT VENOUS CLINICAL SEVERITY SCORE

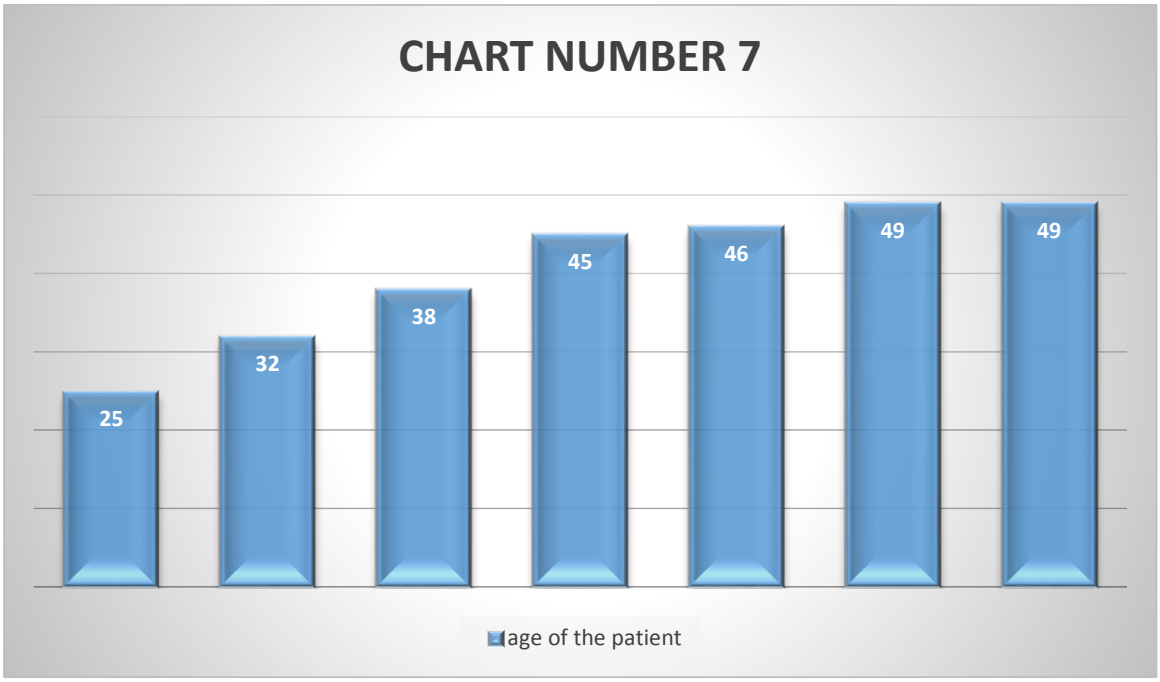
CHART NUMBER 5



PERCENTAGE OF PATIENTS PRESENTING CLINICALLY WITH ACTIVE VENOUS ULCER AND THEIR NUMBER

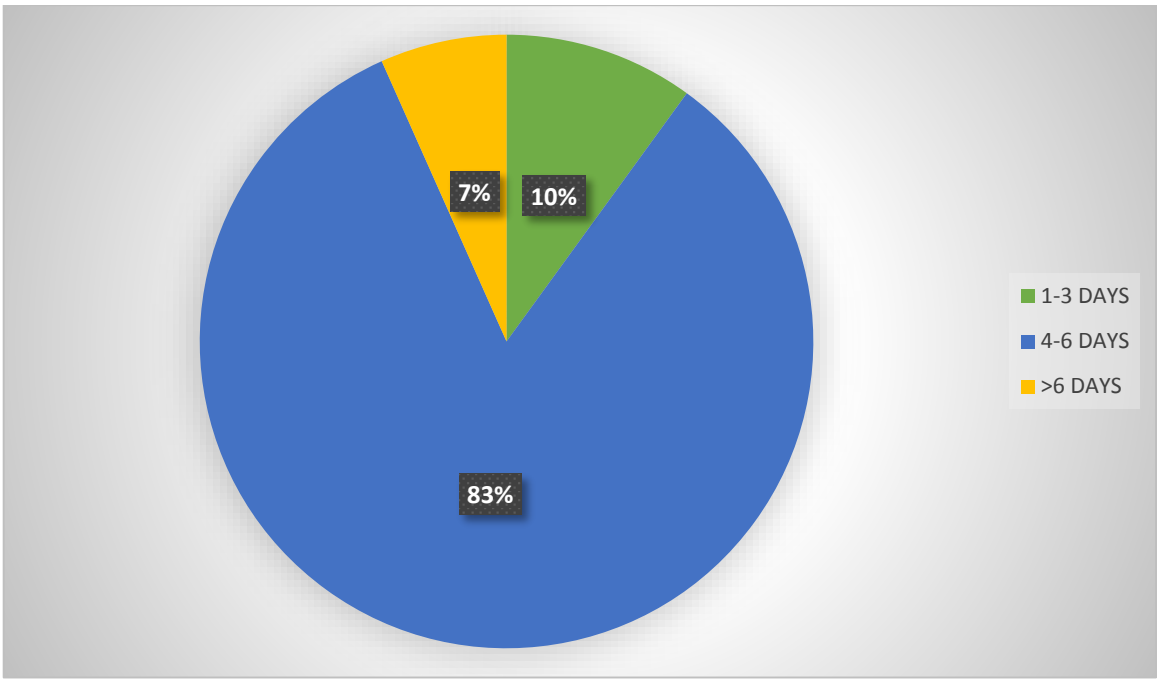


AGE DISTRIBUTION OF ACTIVE ULCER DISEASE IN STUDY POPULATION



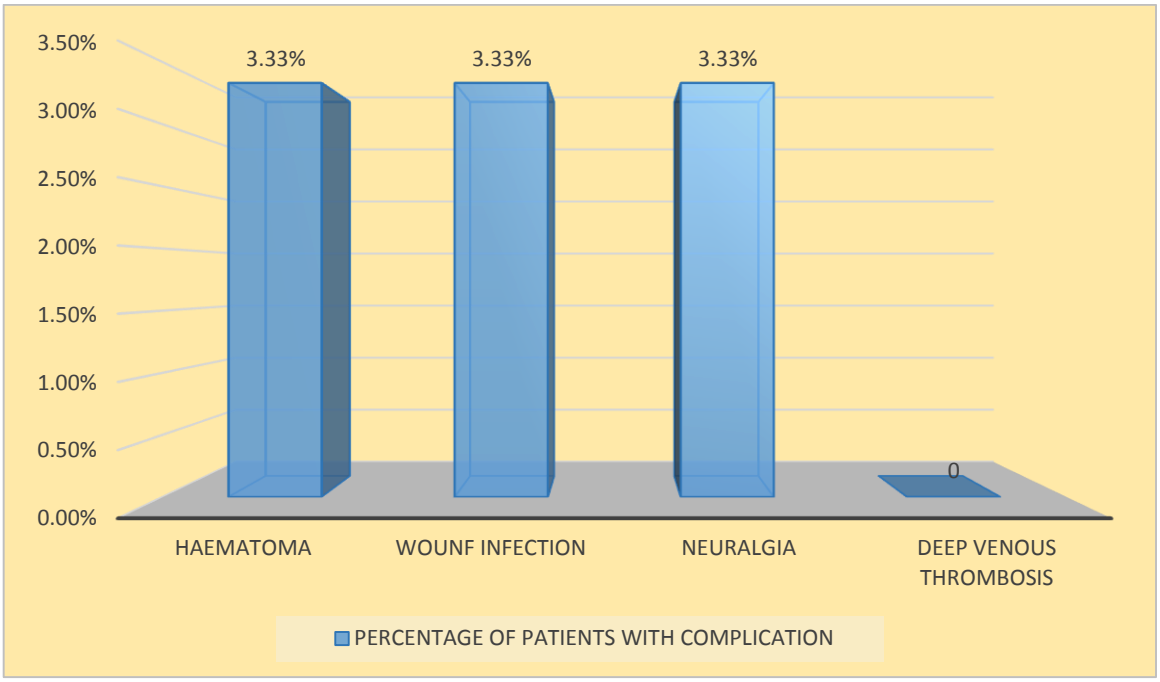
LENGTH OF HOSPITAL STAY:

CHART NUMBER 8

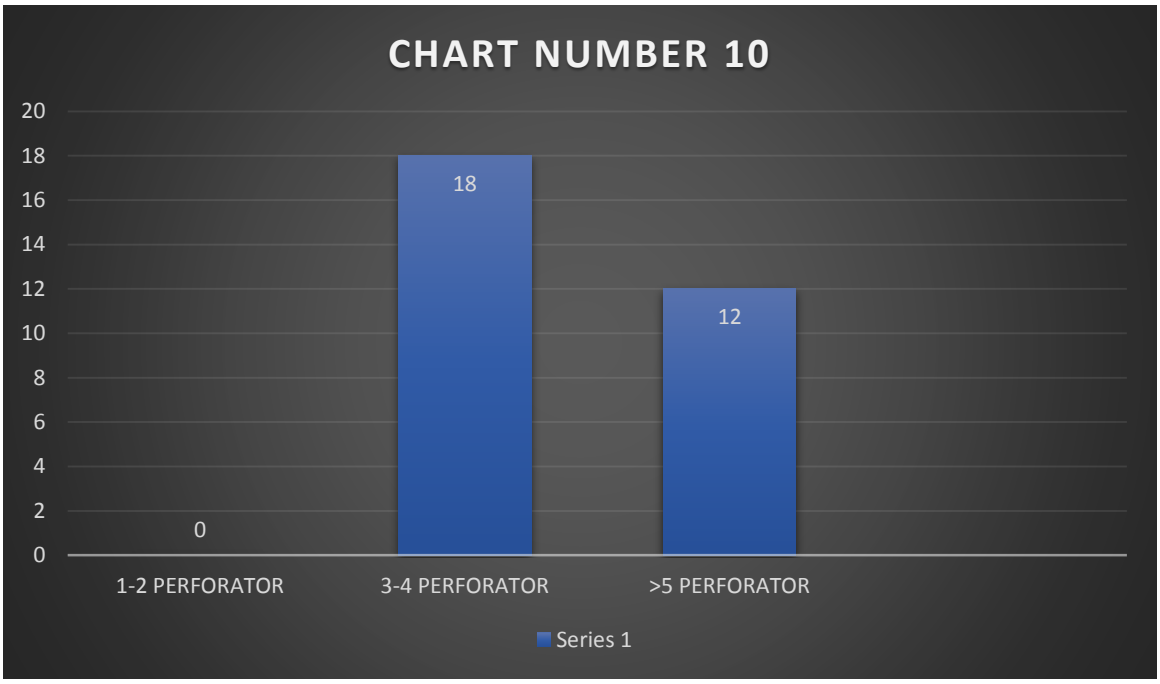


POST OPERATIVE COMPLICATION IN PATIENTS UNDERGOING SUBFASCIAL ENDOSCOPIC PERFORATOE LIGATION SURGERY

CHART NUMBER 9

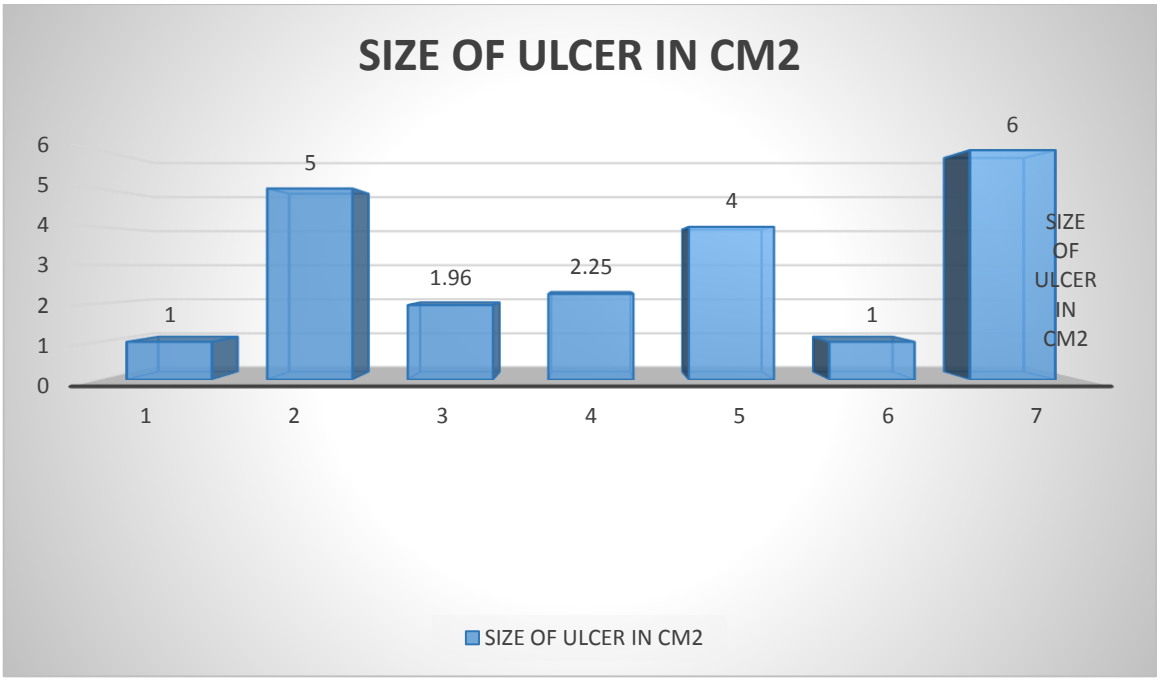


NUMBER OF PERFORATOR DIVISION PERFORMED IN THE PATIENTS UNDER STUDY DURING SEPS

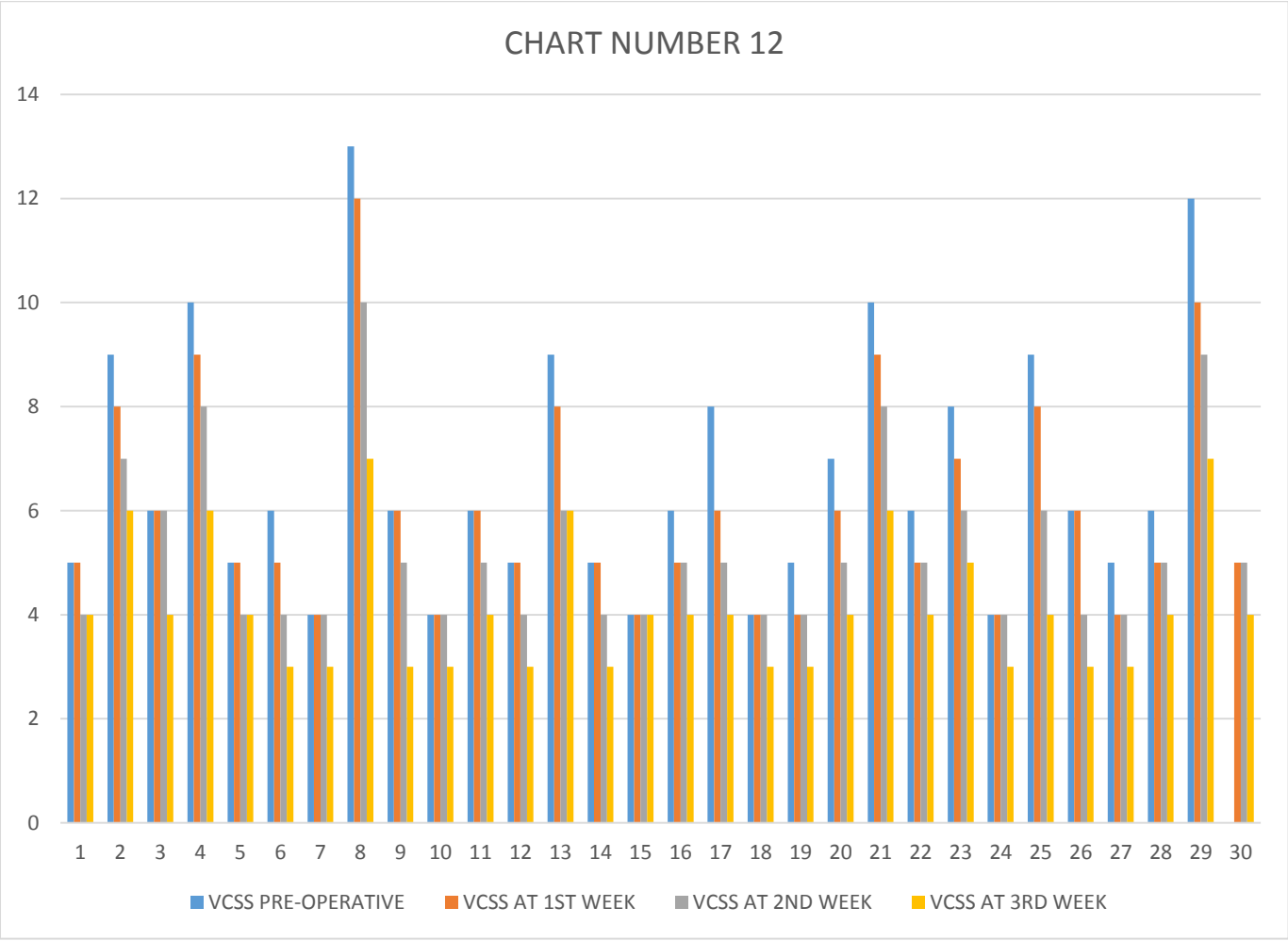


REPRESENTATION OF THE SIZE OF ULCER IN CM2 IN PATIENTS PRESENTING WITH ACTIVE VENOUS ULCERS WITH PERFORATOR IMCOMPETENCE

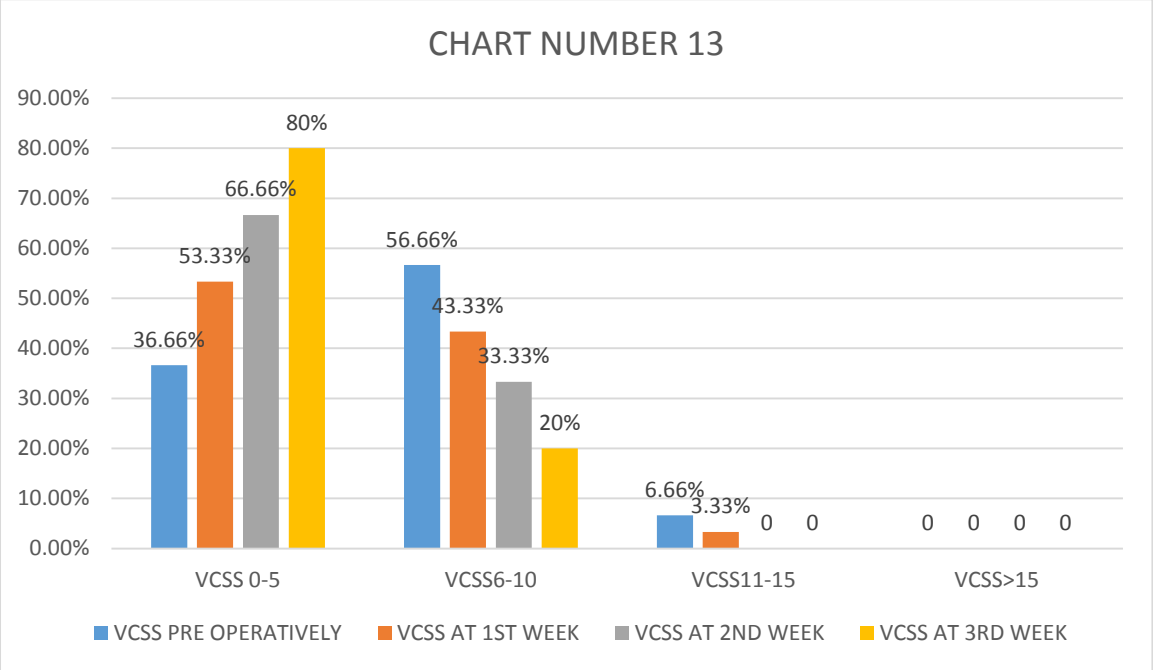
CHART NUMBER 11



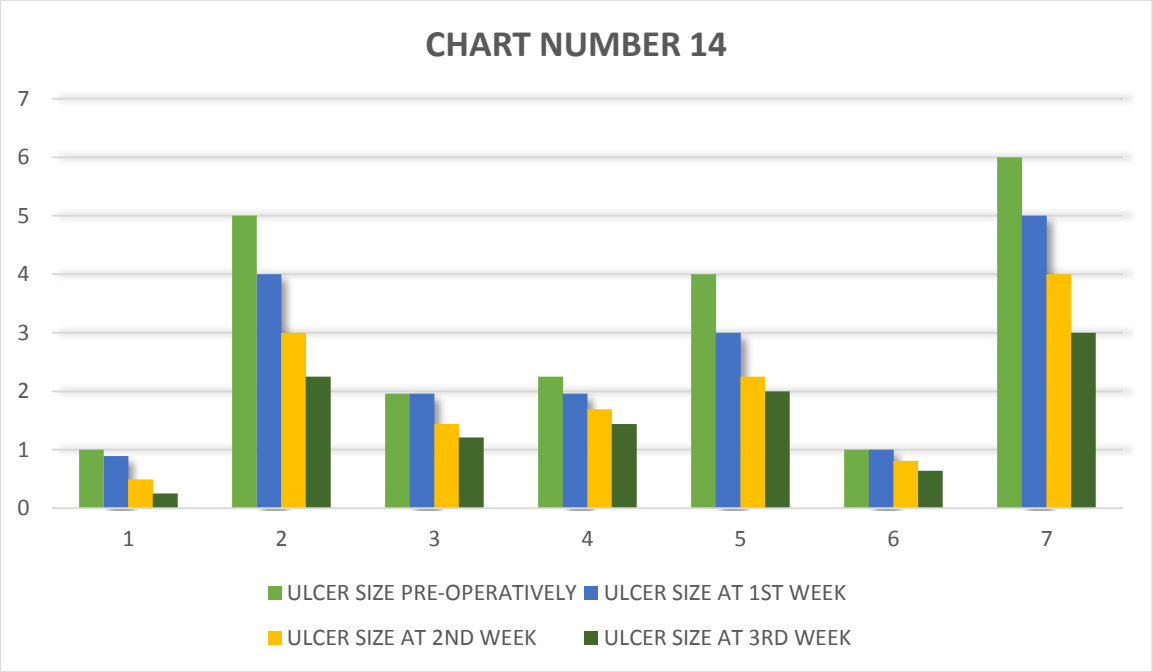
REPRESENTATION OF CLINICAL REDUCTION OF SYMPTOMS POST-OPERETIVELY AT 1 ST WEEK ,2ND WEEK AND 3RD WEEK



REPRESENTATION OF SYMPTOM REDUCTION BY VENOUS CLINICAL SEVERITY SCORE AT 1ST WEEK,2ND WEEK AND 3RD WEEK POST-OPERATIVELY



REPRESENTATION OF ULCER SIZE REDUCTION AT 1ST WEEK, 2ND WEEK AND 3RD WEEK



DATA ANALYSIS:

In our study which included a sample size- 30 Patients with perforator incompetence two third of the patients were male-20 patients (66%) and one-third were female -10 patients (33%)

The ratio of male to female was 2:1(data chart 1)

Two thirds of the patients under the study were in the age group of 30-50 years with equal age distribution amongst patient between 30-40yrs(10 patients) and 40-50yrs(10 patients) (data chart 2)

Three-fourth of the patients presenting with perforator incompetence were in the CEAP classification of class 4 and 5(77%; 23 patients) and one-third of the patients were class 6 category (23%; 7 patients with active ulcer disease (data chart 3)

The mean Venous clinical severity score for a sample size of 30 in our study population was **6.66** (data chart 4)

About 56.66% (17 of the patients) under study had a VCSS score between 6-10 and 36.66% (11 of the patients had a VCSS score between 1-5 and only 6.66% (2 patients) had a VCSS of 11-15 and none above 15(data chart 5)

7 patients amongst the 30 patients had an active ulcer at the time of presentation. 5 patient had a single ulcer. 1 patient had 2 and another had 3 ulcers. (data chart 6)

The mean age of active ulcer disease in our population was 40.7 years of age with a significant history of ulcer formation following trauma a non-healing for a mean time period of 6 weeks (data chart 7)

25 patients(83%) had total hospital stay of 4-6 days; 3(10%) patients had a hospital stay for1-3 days and only 2 (7%)patients had a hospital stay for >6 days for post-operative complication of haematoma and wound site infection(data chart 8)

Three patients (10%) had post- operative complications

1 patient (3.33%) developed haematoma

1 patient (3.33%) had wound infection

1 patient (3.33%) developed neuralgia

All patients were managed conservatively and no repeat procedures were performed in any patients (data chart 9)

In 60% of patients (18 patients) 3-4 perforators were identified and divided and in the rest 40% of patients >5 perforators were divided subfascially at the site where perforators were marked pre-operatively

The mean number of perforators divided in our study were 4.2(data chart 10)

The ulcer size was calculated in cm2 in all patients in our study. In patients with multiple ulcers the mean of summation of size of all ulcers were taken in consideration. And reassessed post- surgery upto 3 weeks. The mean ulcer size for 7 patients with active ulcer disease under our study was 3.3cm2 (data chart 11)

The mean VCSS for the patients under study was 6.66 pre-operatively

The mean VCSS for the patients under study after 1week post SEPS was 6 (10% reduction compared to initial value)

The mean VCSS for the patients under study after 2 weeks post SEPS was 5.33 (19% reduction to pre-operative score)

The mean VCSS for the patients under study after 3 weeks post SEPS was 4.2 (36.9% reduction in clinical severity). So total mean VCSS reduction at the end of 3 weeks post-surgery was 36.9% of the actual mean prior to surgery (data chart 12)

The majority of patients had a VCSS prior to surgery between 6-10 (56.66%) and post-surgery after 3 weeks about 80% of the patients under study had a reduction in clinical symptoms with VCSS less than 5 (data chart 13)

The mean ulcer size in cm2 prior to surgery was 3.3cm2

The mean ulcer size after 1 week post-surgery was 2.544 cm2 which is a size reduction of 22.9% of original mean ulcer size value

The mean ulcer size after 2 weeks post SEPS was 1.95 cm2 which is a size reduction of 40.54%of original mean ulcer size. Finally after 3 weeks post SEPS the mean ulcer size was 1.54% which is a size reduction of 53.33% (data chart 14)

RESULTS

The above data that was obtained from the study, analysis of the data was done using student paired t test

For venous clinical severity scoring pre operatively and after 3 weeks post-surgery, the mean for VCSS pre-operatively was 6.66 and a standard deviation of 2.399. The T value was calculated and was found to be 4.9321 and p value of 0.00001(p value less than 0.05 is significant)

Similarly for the cases with active ulcer, the size assessment pre-operatively and post-SEPS was again analysed using student t test and the mean ulcer size prior to surgery was found to be 3.3 and standard deviation of 1.984. The T value was calculated and was found to be 1.789009 and a p value of 0.04 (p value less than 0.05 is significant)

Hence from the above data it is clear that the p value of the parameters that were evaluated in our study favour a positive and significant clinical outcomes in patients who underwent subfascial endoscopic perforator incompetence for perforator incompetence

DISCUSSION

Our study was a prospective longitudinal study of clinical outcomes of subfascial endoscopic perforator incompetence in a study population of 30 patients with duplex scan confirmed perforator vein incompetence in the CEAP classification of 4, 5 and 6. These patients after obtaining consent from the patients to be included in the study were assessed for two main parameters

1. Venous clinical severity scoring pre-operatively and at 1st, 2nd and 3rd week post-operatively for symptom reduction

2. Ulcer size reduction in size at 1st, 2nd and 3rd week post SEPS

In our study we observed that the majority of the patients about 66% were male and 33% were female. In a study reported by M.G.Vashist and Nitin singhal in Indian journal of surgery 2014[53] also reported that 70 patients out of 100 were males and 30 were females. Synbrandy et al have reported 31% males and 69% females.

Tenbrook et al[35] have compared data from 20 studies and an overall average sex distribution was 51% females and 49% males .The reason for male predominance is our study could be because more number of males turned up for treatment and that it is a male dominant society

In our study we observed that most of our patients (56.66%) were in the age group of 30-50 years with the mean age of 48.6 years. In the study published in Indian journal of surgery 2014 observed that 58 out of 100 patients were in the age group of 16-35 with a mean of 33.6 years

Most patients in our study had a perforator incompetence in the right lower limb (60%) and left side in (25%) and bilateral disease (15%). In case of bilateral disease in the limbs with advanced CEAP and VCSS score were operated. Gloviczki et al[32] reported right sided involvement in 49% patients and left in 46% of patients and bilateral in 5% of patients under study. Hauer et al [26] reported 19% right sided chronic venous insufficiency and 35% on the left side

In our study the mean number of perforators ligated were 4.2. In a study published in Indian journal of surgery by M.G. Vashisht and Nitin singhal[53] a total of 314 perforators were ligated in 100 limbs. Pierik et al divided 54 perforators with the range of 1-6 averaging 2.9 perforators

Jugenheimer et al[33] reported “a total of 456 perforator ligation with a range of 2-11 with an average of 4 per limb”

In our study the most common group of perforators ligated were the Cockett group which were clinically tested to be incompetent were the most accessible group with this procedure

In our study the patients were assessed based on clinical severity scority the mean of which pre-operatively was 6.66 and reduced to 4.2 after 3 weeks post- SEPS (p value .00001). Gloviczki et al [32]USA reported "the results of north American subfascial endoscopic perforator ligation surgery registry[27] which included 146 cases from 17 centres across USA and Canada reported a clinical score improvement of 3.98 from 8.93 for a complete follow up period of 2 yrs". In another study in 2014 by M.G. Vashisht and Nitin Singhal reported that "patients with complaints of pain during walking could walk without feeling discomfort at 14 days after SEPS". Uncu et al[37] in his series of 28 patients observed "improvement in symptom by clinical improvement index after 3 months of SEPS from 8.14v/s 2.54 which was statistically significant". Baron et al noted "decrease in oedema and regression of symptoms with subjective improvement in physical performance in all patients"

In our study we observed that the rate of ulcer size reduction after 21 days of post SEPS was 53.33% (p value of 0.04). Synbrandy et al reported "a ulcer healing rate of 95%after SEPS". Tenbrook et al[35] reported "a median time as 30-60 days for complete healing after SEPS". Baron et al[43] reported "primary healing following SEPS in 41 out of 53 patients in 12 weeks and in the remaining 12 it took longer time but none exceeded 6 months". In a study done Anjay kumar included 21 patients of varicose veins with the perforating vein incompetence underwent SEPS using harmonic scalpel

showed “ulcer healing in 8 weeks with no recurrences in 11.9 month of follow up”. Negus and freugood[25] reported “84% ulcer healing rate”.

In our study 10 % of the patients developed postoperative complications like wound site infection which subsided in 10 days with conservative management,

haematoma formation which resolved in 2 weeks with medical management and dysesthesia in one patient .

Jugenheimer and Junginger et al[33] reported “dysesthesia in 9.7% (n=103 limbs) with severe subfascial infection in 2 (1.9%) patients”. Witten et al [34]reported ‘severe subfascial infection necessitating surgical intervention on both sides’.

Synbrandy et al reported “wound infection in 10% of patients”. Baron et al [43] reported no wound complications in his study. Tenbrook et al[35] reported “9% haematoma formation”

CONCLUSION

Venous ulcers are common cause of long term morbidity and disability. The venous ulcers can be managed by bed rest and limb elevation leading to its healing. The open technique of exploration of the subfascial plane for ligation of incompetent perforating veins leads to delayed wound healing,skin necrosis and wound infection

Hence a less invasive approach like the new endoscopic technique have been developed recently. These endoscopic techniques have an advantage of very minimal post-operative pain with early active mobilization within a few hours after surgery and reduce the morbidity caused due to prolonged immobilization post open surgeries

Endoscopic exploration of subfascial area in patients with venous ulcers results in an uncomplicated primary healing of wound with very low wound complications

These endoscopic procedures not only reduces the post-operative sequelae but also requires small skin incisions for port placement

In a tertiary care centre this procedure of subfascial endoscopic perforator ligation surgery can be performed with available laparoscopic instruments and apparatus

The use of endoscopic technique allows clear identification of nearly all perforators in patients and in patients with advanced chronic venous disease

This technique can also be utilized to perform ligation of the incompetent perforating veins in patients with lipodermatosclerosis (skin thickening and induration) and active

ulcers to identify and ligate the perforators beneath the ulcer site which thus helps in ulcer healing and prevent ulcer recurrences

Endoscopic subfascial division of incompetent perforating veins is a new promising technique and had gained popularity amongst surgeons as surgical treatment of venous ulcers as the trend is now towards minimally invasive surgery

The accessibility of sub-malleolar perforators is feasible with subfascial plane exploration and further enhances the ulcer healing process

SEPS should be an added procedure along with conventional varicose veins surgery in order to reduce long term recurrences of the venous ulcer and promote wound healing

The reasons why SEPS should be considered are

1. Though the outward flow can be abolished by means of surgery, one may assume that the medial calf perforators have been rendered incompetent pre-operatively due to dilatation that would have resulted from the excessive filling of deep venous system from the reflux in superficial venous system. So removal of superficial system may help these perforator gain its normal diameter and competence. But eradication of superficial system surgically can correct reflux in femoral vein presumably due to removal of thigh perforators while performing stripping procedures. But a similar effect of superficial surgery on tibial or popliteal veins is not observed as the calf perforators are left undisturbed
2. The second hypothesis is that the changes in these incompetent perforators competence of the calf perforators is disturbed during multiple calf

phlebectomies inspite of localising these incompetent perforating veins using Doppler study the surety of these perforators cannot be ascertained

3. Another hypothesis is that though the perforators which are incompetent would have been left undisturbed, the outflow from these perforators would have decreased or obstructed. So inspite of long saphenous vein stripping with flush ligation with multiple phlebectomies a sufficient degree of reflux may still persists in the tributaries to maintain perforating vein incompetence

With better understanding of chronic venous disease, the ability to follow the clinically relevant outcomes should increase. The VCSS is considered the progeny of the CEAP clinical class

This scoring system has been shown to be practical and easy one to use to assess the outcomes of treatment. VCSS is an instrument that can be accepted as valid, reliable, and useful by the international venous community. The revised VCSS along with clinical CEAP provides a standard tool and clinical language to document and compare differing approaches to chronic venous disease management.

SEPS not only helps in accurate removal of the incompetent perforators which are the main cause for venous ulcerations but also improves the haemodynamic changes in the deep venous system with reduction in clinical severity of chronic venous disease. The role of SEPS should be considered whenever patients has incompetent perforators along with reflux in superficial system and

also in patients in advanced stages of chronic venous disease like CEAP 4,5 and 6.

Hence with the favourable and significant ulcer healing rate with improvement and reduction in clinical severity suggests that SEPS plays an important role in surgical management of advanced stages of venous insufficiency

ANNEXURE I

CEAP CLASSIFICATION

Clinical presentation	Etiology	Anatomical	Pathophysiology
C0-none	**Ec**-congenital	**As**-superficial	**Pr**-reflux
C1-telangectasia/reticular	**Ep**- primary	**Ap**-perforating vein	**Po**-obstruction
C2-varicose veins	**Es**-secondary	**Ad**-deep	**Pr,o**-reflux +obstruction
C3-oedema		**An**- no venous location identified	**Pn**-no venous pathophysiology identified
C4a-venous eczema	Post thrombotic		
Pigmentation	post traumatic		
C4b-lipodermatosclerosis	-other		
C5-healed ulcer	**En**-no venous cause identified		
C6-open ulcer			

i

ANNEXURE II

VENOUS DISABILITY SCORE

SCORE	DEFINITION
0	Asymptomatic
1	Symptomatic, but able to carry out usual activities with-out compressive therapy
2	Able to carry out usual activities only with compression and/or limb elevation
3	Unable to carry out usual activities even with compression and/or limb elevation

PROFORMA

1. Patient name
2. IP No:
3. Department:
4. Hospital:
5. Age:
6. Sex:
7. Occupation
8. Chief complaints:
9. Past history:
10. Body mass index:

11 General examination

12. **Vitals**

a. Pulse rate:

b. Blood pressure:

c.Temperature:

13. Local examination:

a.Inspection

b.Palpation:

c.Percussion:

d.Auscultation:

14. Abdominal examination

15. Cardiovascular and respiratory system examination

16. Diagnosis:

17. CEAP Classification:

18. Venous disability scoring:

1st week 2nd week 3rd week

19. Venous clinical severity scoring:

1st week 2nd week 3rd week

20. Reduction of ulcer size:

1st week 2nd week 3rd week

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viii

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ஒப்புதல் டிவம்

ஆய்வு செய்னப்டும் தல்ப்பு : கா்ில் இபத்தா்ம் சுருண்டுவதால் ஏற்டும் ிபச்ெல்க்கு இபத்த ா துல்கல் (perforator incompetance) ல்ப்பாஸ்லகா்ி முல்
டி ெரி செய்வலத ற்்ின ஆய்வு ஆய்வு செய்னப்டும் துல்

: சாது அறுலவ ெிகிச்லெதுல்

நருத்துவநல் : கீழ்ாக்கம் அபசு நருத்துவக்கல்லூரி நருத்துவநல்

ங்கு சறுவரின் சனர் :

ங்கு சறுவரின் வனது :

ங்கு சறுவரின் நருத்துவநல்
எண் :

ங்கு சறுவர் இதல் (✓) குிக்கவும் :

1. கா்ில் இபத்தா்ம் சுருண்டுவதால் ஏற்டும் ிபச்ெல்க்கு இபத்த ா துல்கல் (perforator incompetance) ல்ப்பாஸ்லகா்ி முல் டி ெரி செய்வலத ற்்ின ஆய்வின் விவபங்கள் எக்கு சத்ிவாக வி்க்கப்ட்டது. என்னுலடன ெந்லதகங்கல் லகட்கவும் அதற்கா் வி்க்கங்கல் ச்வும் வாய்ப்பு அ்ிக்கப்ிட்டுள்து எ அ்ிந்து சகாண்லடன். ( )
2. ான் இந்த ஆய்வில் தன்ிச்செனாக தான் ங்லகற்கிலன். எந்த காபணத்தி்ாலா ான் இந்த ஆய்வில் இருந்து வி்க ஆலெப்ட்டால் எந்த ிபச்ெல்யும் இன்ி வி்கா்ாம் என்றும் அ்ிந்து சகாண்லடன். ( )
3. இந்த ஆய்வு ெம்ந்தநாகலவா , இலத ொர்ந்த லநலும் ஆய்வு லநற்சகாள்ல்ம் சாழுலதா இந்த ஆய்வில் ங்கு சரும் நருத்துவர் என்னுலடன நருத்துவ அ்ிக்லகல் ார்ப்தற்கு என் அனுநதி லதலவ இல்ல் எ அ்ிந்லதன்.( ) 4. இந்த ஆய்வில் ங்கு சகாள் ான் சுன ிலலவாடும் முழு ெம்நதத்லதாடும் ஒப்புதல் அ்ிக்கிலன். ( )

ங்கு சறுவரின் ஆய்வாரின் சனர் : சனர் :

□ங்கு ச□று□வரின் லகசனாப்□ம் :

வி□ாெம் :

ஆய்வா□ரின் லகசனாப்□ம்:

லததி :

இடம் :

MASTER CHART

NO +O 23J	IP NO	AGE/ SEX	CEAP	VCSS	NO OF ULCERS	ULCER SIZE	NO OF PERFORATOR LIGATED	HOSPITAL STAY	POST OP COMPLICATIONS	VCSS 1ST WEEK	VCSS 2ND WEEK	VCSS 3RD WEEK	ULCER SIZE 1ST WEEK	ULCER SIZE 2ND WK	ULCER SIZE 3RD WEEK
1	10438	38/F	4	5			4	4	-	5	4	4			
2	11416	42/M	5	9			3	5	-	8	7	6			
3	11890	60/M	4	6			4	3	-	6	6	4			
4	12543	38/M	6	10	1	1cm2	5	5	-	9	8	6	0.89CM2	0.49CM2	.25CM2
5	12673	36/F	4	5			3	4	-	5	5	4			
6	13470	63/F	5	6			4	5	-	5	4	3			
7	13906	48/M	5	4			5	4	-	4	4	3			
8	14589	25/M	6	13	3	5cm2	5	3	-	12	10	7	4CM2	3CM2	2.25CM2
9	15009	29/F	5	6			4	5		6	5	4			
10	15732	52/F	4	4			3	4	-	4	4	3			
11	16111	33/F	4	6			4	5	-	6	6	5			
12	16091	44/M	4	5			3	4	HAEMATOMA	5	4	3			
13	17001	49/M	6	9	1	1.96CM2	5	5	-	8	6	6	1.96CM2	1.44CM2	1.21CM2
14	17423	39/M	5	5			3	4	-	5	4	3			
15	17993	60/M	4	4			5	4		4	4	4			
16	18003	45/F	5	6			4	5	-	5	5	4			
17	18556	37/M	6	8	1	2.25CM2	4	5	-	6	5	4	1.96CM2	1.69CM2	1.44CM2
18	18723	46/M	5	4			5	7	WOUND INFECTION	4	4	3			
19	19662	38/M	4	5			4	4	-	4	4	3			
20	20041	49/M	5	7			4	5	-	6	5	4			
21	22034	41/F	6	10	2	4CM2	5	6	-	9	8	6	3CM2	2.25CM2	2CM2
22	23764	32/M	4	6			4	4	-	5	5	4			
23	24881	28/M	6	8	1	1CM2	4	5	-	7	6	5	1CM2	0.81CM2	0.64CM2
24	26754	62/M	4	4			3	3	-	4	4	3			
25	27396	56/F	5	9			3	4	-	8	6	4	1.5CM2	1.2CM2	0.64CM2
26	28101	34/M	5	6			4	5	-	6	4	3			
27	29333	37/F	4	5			4	4	NEURALGIA	4	4	3			
28	26003	46/M	4	6			4	5	-	5	5	4			
29	28541	29/M	6	12	1	6CM2	5	8	-	10	9	7	5CM2	4CM2	3CM2
30	27431	45/M	5	6			4	5	-	5	5	4			